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## Patents on People and the U.S. Constitution: Creating Slaves or Enslaving Science

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# NOTES

## Patents on People and the U.S. Constitution: Creating Slaves or Enslaving Science?

*[M]an's power over Nature turns out to be a power exercised by some men over other men with Nature as its instrument.*

C. S. Lewis<sup>1</sup>

### Introduction

Genetic engineering technologies have emerged from the laboratory to meet the needs of the marketplace. Products of biotechnology hold promise for increasing world food supplies, curing fatal viral infections, producing pollution-free fuels, and curing lethal hereditary disorders.<sup>2</sup> Not long ago the genes of bacteria were the subject of experiments; now scientists are capable of manipulating genes of most multi-cellular animals.<sup>3</sup>

One contemplated use of such genetic engineering<sup>4</sup> is splicing a gene or several genes from one organism into another organism's DNA<sup>5</sup> to

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1. ABOLITION OF MAN 69 (1947).

2. More than 2000 human disorders have been found to result from mutations of a single gene. V. MCKUSICK, MENDELIAN INHERITANCE IN MAN (7th ed. 1986). One such disease, thalassemia, is caused by inadequate production of one of the two components of hemoglobin, alpha and beta globin. Thalassemia claims the lives of 200,000 children annually. *Human Genetic Engineering: Hearings Before the Subcommittee on Investigations and Oversight of the House Committee on Science and Technology*, 97th Cong., 2d Sess. 232 (1982) [hereinafter *Human Genetic Engineering Hearings*] (statement of Dr. Zsolt Harsanyi, VP E.F. Hutton & Co., citing a report published in 298 *Nature*, at 416 (Nov. 16, 1982)). Children born with the disease usually don't live longer than 20 years, despite blood transfusion treatments. *Id.* at 233.

3. Experiments in human gene transplants, however, have been delayed due to "unresolved questions." The proposed experiments would genetically alter human blood cells, allowing scientists to assess the effectiveness of certain cancer treatments. *N.Y. Times*, Oct. 20, 1988, at A11, col. 1 (national ed.).

4. "Genetic engineering" can be used to describe one or more techniques used either alone or in combination. For the purposes of this note it will refer to recombinant DNA technology only. For a description of recombinant DNA technology, see *infra* text accompanying note 31.

5. DNA (deoxyribonucleic acid) is the genetic material contained in living cells. The cells of mammals contain dozens of chain-like molecules of DNA clustered together in chro-

create a new life form.<sup>6</sup> While currently employed in animals,<sup>7</sup> in the future this technology might be used to create new forms of human life.<sup>8</sup> Like innovations in inanimate materials, genetically engineered life forms are inventions.<sup>9</sup> As genetic scientists develop new ways to refashion living organisms, they will seek to shield the fruits of their research efforts from competitors. United States patent laws will most likely be invoked to provide such protection.

A genetic scientist might, for example, attempt to patent a genotype<sup>10</sup> that will produce unique traits.<sup>11</sup> Implanting a spliced DNA molecule containing genetic material from another source into an embryo's

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mosomes. See Crick, *The Genetic Code: III* (October 1966), reprinted in *SCIENTIFIC AMERICAN, RECOMBINANT DNA* (1978).

6. Insertion of human genetic material into fertilized mouse eggs has resulted in producing creatures that have never before existed. The offspring carry a hybrid gene, comprised of human and mouse genetic components, that directs the production of TPA, a naturally occurring protein in human blood. Female offspring with the hybrid gene produce TPA in their milk and pass this trait on to future generations. Used in the treatment of heart attacks and hemophilia, TPA is difficult and expensive to produce by more conventional methods. Genetic engineering technology also may soon be used in sheep, cows, and goats to produce large quantities of medically important proteins. Integrated Genetics Inc., Washington, D.C., Press Release (Oct. 26, 1987).

7. See N.Y. Times, June 8, 1987, at A1, col. 3 (transgenic pig possessing gene spliced from cow produces offspring that are leaner and grow faster); N.Y. Times, April 13, 1988, at A1, col. 1. (United States Patent No. 4,736,866 issued for new breed of genetically altered mice to be used in cancer research).

8. Dr. J.B.S. Haldane has suggested several possibilities for artificially altering human genetic make-up in the future. One scenario involves grafting genetic material from other species onto human cells. Animals possessing desirable characteristics, such as superior olfactory capacities or loose skin that heals, with little scarring, might be used in hybridization. Gene-grafting might make it possible to develop human astronauts equipped with prehensile feet, no heels, and an ape-like pelvis suitable for life in the low gravity and cramped quarters of a space ship. Human visitors to a high gravitational field such as that of Jupiter would fare better if they were short-legged or quadrupedal. Haldane, *Biological Possibilities for the Human Species in the Next Ten Thousand Years*, in *MAN AND HIS FUTURE* 337, 354-55 (G. Wolstenholme ed. 1963); see Note, *Asexual Reproduction and Genetic Engineering: A Constitutional Assessment of the Technology of Cloning*, 47 S. CAL. L. REV. 476, 520 (1974).

Genetic manipulation of such magnitude and complexity in humans is beyond the scope of both this note and the technical competence of the author. Any regulation of genetic engineering technology, however, will influence which products and procedures will be derived from the fields of genetics and biomedical engineering in the future. It is, therefore, critical that such regulation be chosen carefully.

9. See *Diamond v. Chakrabarty*, 447 U.S. 303 (1980).

10. "Genotype" refers to an organism's specific genetic constitution or the composition of one or a limited number of genes under investigation. W. KLUG & M. CUMMINGS, *CONCEPTS OF GENETICS* 589 (1983). For the purpose of this note, genotype will be used to refer to the product of a scientist's genetic intervention that is the subject of the patent application.

11. An embryo produced by genetic manipulation might meet the novelty requirement of patentability under 35 U.S.C. § 101 if the embryo possessed a unique genotype. See *Diamond v. Chakrabarty*, 447 U.S. 303 (1980); *Ex parte Allen*, 2 U.S.P.Q. 2d 1425 (PTO Bd. App. & Int. 1987) *aff'd*, 846 F.2d 77 (Fed. Cir. 1988).

cells would produce an organism with traits that the scientist has chosen. One day such recombinant DNA techniques may be used in human embryos to treat genetic diseases by correcting defective genes, or even to accentuate certain desirable characteristics such as height, intelligence, or eye color. The prospect of obtaining patents for their inventions will encourage scientists to pursue genetic research that may lead to cures for illnesses that presently leave the afflicted without much hope. But the United States Patent and Trademark Office (PTO) has attempted to block the patenting of genetically engineered human genotypes and its action could slow the pace of such medical advances.

On April 7, 1987, the PTO proclaimed that "[a] claim directed to or including within its scope a human being will not be considered to be patentable" because the grant of an exclusive property right in a human being "is prohibited by the Constitution."<sup>12</sup> Despite this proclamation, the patentability of human inventions<sup>13</sup> remains an unsettled question, both because the PTO did not detail the grounds for its position and because the PTO policy appears to rest on constitutional issues it lacks the authority to resolve.

In exploring the constitutionality of patenting human genetic engineering products, this Note examines three issues: first, whether granting a person patent rights in genetic material implanted in another human being infringes fundamental freedoms protected by the Constitution; second, whether the patent holder's exercise of his patent rights violates the constitutional rights of those who are born with patented genes contained within their cells; and third, whether potential unconstitutional applications of patented human inventions would render such inventions unpatentable.

Section I of this note examines the characteristics of a patent and concludes that a scientist's property rights in his invention of a novel

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12. The PTO's policy was published in a statement by Donald J. Quigg, Assistant Secretary and Commissioner of the United States Patent and Trademark Office, April 7, 1987 [hereinafter PTO Statement]. The relevant portions of the statement read as follows:

A claim directed to or including within its scope a human being will not be considered to be patentable subject matter under 35 U.S.C. 101. The grant of a limited, but exclusive property right in a human being is prohibited by the Constitution. Accordingly, it is suggested that any claim directed to a non-plant multicellular organism which would include a human being within its scope include the limitation 'non-human' to avoid this ground of rejection . . . . To the extent that the claimed subject matter is directed to a non-human 'nonnaturally occurring manufacture or composition of matter—a product of human ingenuity' (*Diamond v. Chakrabarty* [447 U.S. 303 (1980)]), such claims will not be rejected under 35 U.S.C. 101 as being directed to nonstatutory subject matter.

13. A "human invention" is used here to mean an invention involving a human genotype that meets the statutory patent requirements and expresses a distinct phenotype, that is—a genetically determined characteristic or trait—whether discernible to observers or not. A human invention may include claims to genetic manipulation in human embryos as well as in persons already born. See *infra* notes 32-33 and accompanying text.

human genotype by themselves would not violate the Thirteenth Amendment. Section II considers the constitutionality of an inventor's practice of his patent.<sup>14</sup> The discussion centers on how the manufacture of patented human genotypes might infringe basic constitutional protections of the individuals possessing the patented genetic material. Section III assesses how the availability of patented products of human genetic engineering technology could lead to private discriminatory actions and state actions mandating genetic alterations within the populace. Section IV analyzes U.S. patent statutes to determine whether the possibility of unconstitutional consequences of patenting human genotypes is a sufficient ground to deny patents on such inventions. Finally, section V suggests regulatory measures that could ameliorate the constitutional problems presented by such patents.

Denying patents on inventions that involve human beings will shift research efforts away from human genetic engineering technologies and toward technologies that will lead to the development of products that are protected under patent laws. On the other hand, allowing patented inventions involving human beings to be manufactured may threaten constitutional interests. While the PTO's policy reflects an antipathy for new technologies whose implications may cut deeply against the grain of our traditional values, it also presents profound and far-reaching consequences for scientific progress and the future of biotechnology. Because future biological inventions will require lawmakers to examine deep-seated notions of the sanctity of life<sup>15</sup> and the integrity of species,<sup>16</sup> the administration of the patent system will determine how certain fundamental constitutional interests are to be balanced.

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14. Practice of the patent refers to the manner in which the patentee has chosen to exercise the statutory rights granted under the patent.

15. Patenting is the first step toward a "brave new world [where life may be reclassified and reduced] to chemical programs." *Patents and the Constitution: Transgenic Animals: Hearings Before the Subcommittee on Courts, Civil Liberties, and the Administration of Justice, Committee on the Judiciary, House of Representatives*, 100th Cong., 1st Sess. 23 (1987) [hereinafter *Patent Hearings*] (testimony of Jeremy Rifkin, President, Foundation on Economic Trends). "[U]se of genetic human traits in animals . . . [and t]he potential for patenting and owning of animals with human traits brings up the ethical dilemma of the potential of the creation of semihuman creatures which could be patented and sold." H.R. 1827, amend. no. 245, 100th Cong., 1st Sess., CONG. REC. S7269 (daily ed. May 28 1987) (statement by Sen. Hatfield).

16. A. Hoyt, President of the Humane Society of the United States, has observed that "patenting . . . would . . . result in monopoly of genetic stock [and a] predominance of certain genetic lines . . . over others, with an ultimate loss of genetic diversity within a species," leading to "adverse social, ecological and economic consequences." *Patent Hearings*, *supra* note 15, at 23.

## I. Patent Rights and Human Subject Matter

Patent laws encourage scientists to develop new inventions<sup>17</sup> and promote the growth of new industries.<sup>18</sup> Patents are available only for new and useful inventions that in some way expand society's accumulated collective knowledge base. In exchange for public disclosure of the invention, a patent grants an inventor a limited monopoly in her invention for seventeen years.<sup>19</sup> Dissemination of technical information that otherwise would remain secret stimulates innovation in fields related to patented technologies, which in turn introduce new products and manufacturing processes.

### A. Statutory Criteria For Patentable Inventions

Patents, governed by Title 35 of the United States Code,<sup>20</sup> grant an inventor exclusive rights to make, use, and sell the invention for seventeen years in exchange for public disclosure of how to make and use the invention.<sup>21</sup> Full expression of Congress' intent to restrict patenting of any invention is contained within Title 35 of the United States Code,<sup>22</sup> which requires that subject matter otherwise patentable<sup>23</sup> must also meet requirements of novelty,<sup>24</sup> usefulness,<sup>25</sup> and nonobviousness.<sup>26</sup> In order to receive a patent for an invention that meets these statutory criteria, the applicant must particularly describe the elements of the invention for which she seeks patent protection.<sup>27</sup> The inventor must also disclose how to make the invention.<sup>28</sup> Because inventions involving biological material often cannot be described in sufficient detail in writing, the inventor must place the invention itself in a publicly accessible depository

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17. See *Kewanee Oil Co. v. Bicon Corp.*, 416 U.S. 470 (1974); *Universal Oil Co. v. Globe Co.*, 322 U.S. 471 (1944).

18. The United States patent system is a dominant force influencing the commercialization of new biotechnology products. U.S. CONGRESS, OFFICE OF TECHNOLOGY ASSESSMENT, *COMMERCIAL BIOTECHNOLOGY: AN INTERNATIONAL ANALYSIS (SUMMARY)* 13 (1984).

19. 35 U.S.C.A. § 154 (West 1984).

20. Patent Act of 1952, 35 U.S.C.A. §§ 1-272 (West 1984).

21. *Id.* § 154.

22. *Graham v. John Deere Co.*, 383 U.S. 1, 12 (1966). All conditions of patentability are contained within the code: "[An inventor] may obtain a patent [for an invention] subject to the conditions and requirements of *this* title." 35 U.S.C.A. § 101 West 1984 (emphasis added).

23. Patentable subject matter includes a machine, manufacture, or composition of matter. 35 U.S.C.A. § 101 (West 1984). See *Diamond v. Chakrabarty*, 447 U.S. 303 (1980) (living material held to be patentable composition of matter).

24. 35 U.S.C.A. §§ 101, 102 (West 1984).

25. *Id.* §§ 101, 112.

26. *Id.* § 103.

27. The description must be sufficiently "full, clear, concise and [in] exact terms" such that "a person skilled in the relevant technology [can] make and use the invention." *Id.* § 112.

28. "The specification . . . shall set forth the best mode contemplated by the inventor of carrying out his invention." *Id.*

for the entire term of the patent.<sup>29</sup>

Like inventions involving nonliving and nonhuman subject matter, a human invention that meets the statutory criteria would be patentable under current patent laws. Patentable human inventions might include novel genotypes that code for, or express, useful and nonobvious phenotypes.<sup>30</sup> Such novel genotypes would be created by surgical procedures performed on human embryos or existing individuals.

Recombinant DNA technology, or gene-splicing, involves obtaining a strand of DNA from one organism and isolating a precise fragment containing desired genetic information. The fragment is then linked to a second piece of DNA (from the same organism or a different one). Next, the recombined molecules are returned to the nucleus cell from which the DNA was initially removed. The inserted genetic material permanently alters the organism's DNA. The trait produced in the organism by the recombined DNA is reproduced in succeeding generations.<sup>31</sup>

Human inventions would likely employ prenatal<sup>32</sup> and postnatal genetic therapy<sup>33</sup> to correct existing genetic defects (genetic surgery), to create certain genetic characteristics (e.g., hair color, height), or to alter certain human traits (e.g., intelligence, personality). Human hybrids or

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29. *Id.* § 114. See *Feldman v. Aunstrup*, 517 F.2d 1351, 186 U.S.P.Q. 108 (C.C.P.A. 1975), *cert. denied*, 424 U.S. 912 (1976); *Ex parte Argoudelis*, 434 F.2d 1390, 168 U.S.P.Q. 99 (C.C.P.A. 1970); see also *In re Lundak*, 227 U.S.P.Q. 90 (1985). Yet, as patents on genetically engineered animals are granted, deposit as a means of describing the invention will become impractical. "[I]nventions relating to the development of animals having new and otherwise patentable characteristics will rely on the identification and description of a known and readily available animal that will be treated in a reproducible process to obtain the new animal variety. The PTO is presently not aware of any organization that is willing and able to undertake the responsibilities of a suitable depository for live animals." 52 Fed. Reg. 34081 (1987) (to be codified at 37 C.F.R. pt. 1) (proposed Sept. 9, 1987). Similar problems are sure to arise when humans become the subject of patents. New methods of disclosure will have to be devised to assist inventors of such products of human genetic engineering in complying with the statutory criteria.

30. Phenotypes are the observable characteristics or traits of a being that are genetically controlled and determined by the genotype. W. KLUG & M. CUMMINGS, *supra* note 10, at 592.

31. PRESIDENT'S COMMISSION FOR THE STUDY OF ETHICAL PROBLEMS IN MEDICINE AND BIOMEDICAL AND BEHAVIORAL SCIENCE, *SPlicing LIFE: A REPORT ON THE SOCIAL AND ETHICAL ISSUES OF GENETIC ENGINEERING WITH HUMAN BEINGS* 46 (1982) [hereinafter *SPlicing LIFE*].

32. Prenatal gene therapy involves alteration or replacement of certain genes in every cell of every tissue within an organism. Performing gene therapy on an embryo would involve insertion of the desired gene into the mature ovum removed from a woman. The egg is then fertilized in vitro, and implanted in the woman's uterus. This technique would be employed to treat genetic diseases, such as cystic fibrosis, which affect many of the body's organs. *Id.* at 45-46.

33. Post-natal genetic therapy is performed on a fully formed child or adult and involves the alteration of genetic material within a single tissue. Tissue is removed from the patient, desired genes are inserted in place of the patient's original genetic material, and the tissue is then returned to the patient. *Id.* at 42-43.

sub-humans might be created by splicing human genetic material with that of a lower animal to produce an animal-human hybrid or altering human DNA to produce certain "desired" disabilities (e.g., lower intelligence, docile personality).

Myriad human inventions would be patentable. For example, a scientist might seek patent protection for a genotype produced by correcting a defective gene. In addition to eliminating the genetic disorder, the resulting genotype also expresses a phenotype that leaves the individual with a heightened immunity to contagious diseases. In order to assess whether the scientist's invention is patentable, the genotype would have to meet the statutory requirements of novelty, usefulness, and nonobviousness.

The genotype would be novel if the scientist were the first to conceive of the genotype and to reduce it to practice.<sup>34</sup> Reduction to practice involves either creating the genotype and implanting it in a human being or describing in a patent application the arrangement of the newly created DNA molecule. The scientist would likely become aware of the benefits of the resulting phenotype through experiments in which the engineered gene is implanted in a human subject.<sup>35</sup> The novelty requirement would be met when the scientist first conceives of the new genotype and implements the idea.<sup>36</sup>

To qualify for patent protection, the novel genotype would also have to be both useful and nonobvious. A genotype that corrected a genetic disorder would likely meet the usefulness requirement, but would not necessarily be nonobvious. To satisfy this third criterion, the genotype would have to represent a significant departure from all existing and nat-

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34. At the time the scientist makes her discovery and within twelve months of filing her patent application, the same genetic composition must not have been previously patented, must have been unknown to others in the United States, and must not have been described in a document published anywhere in the world. 35 U.S.C.A. §§ 102(a), (b) (West 1984). In addition, the scientist must be the sole inventor of the genotype, must not have received a patent in a foreign country prior to filing her patent application with the PTO, and must not have abandoned her invention. *Id.* §§ 102(c), (d), (f).

35. For discussions concerning genetic experiments on human beings, see Kass, *Babies by Means of in Vitro Fertilization: Unethical Experiments on the Unborn?*, 285 NEW ENG. J. MED. 1174 (1971) (performing risk-filled experiments on the unborn presents the possibility of producing genetic deformities); Note, *State Prohibition of Fetal Experimentation and the Fundamental Right to Privacy*, 88 COLUM. L. REV. 1073 (1988) (arguing laws prohibiting fetal experimentation unconstitutionally impinge on right to privacy in reproductive decisions of couples and women).

36. Genetically engineered animal genotypes have been found to be sufficiently novel and patentable. *Diamond v. Chakrabarty*, 447 U.S. 303 (1980). Therefore, new genetically engineered human genotypes would also be sufficiently novel to meet the statutory criteria. The scientist must, however, file her patent application within one year of her first nonexperimental creation of the genotype in a human subject. The patent statute bars the patenting of inventions that are the subject of a "public use" or "sale" more than one year prior to the patent application date on the grounds of lack of novelty. 35 U.S.C.A. § 102(b) (West 1984).



urally occurring human genotypes. Although correction of a genetic defect that produced the same genotype possessed by all humans without the disorder would not constitute such a departure, a genotype that coded for a unique characteristic or significantly improved existing human traits might. Thus a genotype that produced enhanced immunity to disease would likely meet the nonobviousness requirement, and would probably also meet the usefulness requirement.

Assuming the scientist is able to meet the disclosure and enablement requirements by making a deposit of the genetic material sought to be patented, the only remaining barrier to patent protection would be the statutory subject matter requirement.<sup>37</sup> In 1980, the U.S. Supreme Court ruled that living material created by humans through genetic intervention is a composition of matter constituting patentable subject matter.<sup>38</sup> The Board of Patent Appeals and Interferences recently extended the Court's ruling to include multicellular animals.<sup>39</sup> Given the Supreme Court's statement that statutory subject matter includes "anything under the sun that is made by man,"<sup>40</sup> human inventions would seem to be patentable subject matter. The PTO, however, has stated that "a human being will not be considered to be patentable subject matter under 35 U.S.C. 101" because "[t]he grant of a limited, but exclusive property right in a human being is prohibited by the Constitution."<sup>41</sup>

Yet patented human inventions would cover altered genetic material only, not the individual possessing the novel genotype. And the U.S. Constitution does not prohibit patenting human genotypes. The PTO does not refer in its policy statement to particular provisions in the Constitution that prohibit such patents. Commentators suggest the PTO is relying on the Thirteenth Amendment<sup>42</sup> for constitutional foundation.<sup>43</sup>

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37. See *supra* note 23.

38. *Diamond v. Chakrabarty*, 477 U.S. 303 (1980) (single cell bacterium genetically altered to create a new life form).

39. *Ex parte Allen*, 2 U.S.P.Q.2d 1425 (P.T.O. Bd. App. & Int. 1987) *aff'd*, 846 F.2d 77 (Fed. Cir. 1988), held that polyploid Pacific oysters are patentable subject matter. The patent claim to the oysters, however, was denied on grounds of obviousness. Approximately 30 patent applications involving new animal life forms are presently pending before the U.S. Patent and Trademark Office. Telephone conversation with U.S. Patent and Trademark Office's Public Affairs department, March 10, 1989.

40. *Diamond*, 477 U.S. at 303.

41. PTO Statement, *supra* note 12.

42. "Neither slavery nor involuntary servitude, except as a punishment for crime whereof the party shall have been duly convicted, shall exist within the United States, or any place subject to their jurisdiction." U.S. CONST., amend. XIII, § 1.

43. *LEGAL TIMES*, June 15, 1987, at 16, col. 1. In addition, this writer suggests the PTO may be looking to the Privileges and Immunities Clause of the Fourteenth Amendment. It would appear that an individual, possessing patented genetic material, would be entitled to the constitutional protections that allowing patents on human inventions might infringe, but the effect of the patented gene's phenotypic expression on a plaintiff's ability to successfully plead a constitutional violation resulting from genetic therapy is beyond the scope of this Note.

Presumably, the PTO is equating an inventor's ownership rights in a patent with ownership of the patented article; additionally, the PTO may fear that those born with patented genes will be considered "manufactured." The next section demonstrates that patenting human genotypes will not result in the subjugation prohibited by the Thirteenth Amendment's protections against slavery and involuntary servitude.

## B. Property Rights in People?

A genetic scientist's ability to patent a novel manipulation of DNA in a human genotype would seem to have little connection with General Robert E. Lee's surrender at Appomattox. Yet the Thirteenth Amendment, ratified six months after Appomattox, may control whether human patents are constitutional. In addition to emancipating all persons held in slavery in the United States, the Thirteenth Amendment provided Congress broad enforcement powers.<sup>44</sup> These powers were subsequently exercised to give effect to the emancipation<sup>45</sup> and prohibit subjugation of one person by another.

Congress' power goes beyond protecting the rights of emancipated slaves during the period of reconstruction and extends to eliminating private and state actions that constitute "badges of slavery" or "relic[s] of slavery."<sup>46</sup> The Supreme Court has not only found a violation of the Thirteenth Amendment in activities involving peonage,<sup>47</sup> but has also found badges of slavery in racial discrimination.<sup>48</sup> In addition, courts have invoked the Thirteenth Amendment to prohibit threats of legal confinement and acts short of forced labor.<sup>49</sup>

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44. "Congress shall have power to enforce this article by appropriate legislation." U.S. CONST., AMEND. XIII, § 2; see Civil Rights Cases, 109 U.S. 3, 20 (1883) (Congress has "power to pass all laws necessary and proper for abolishing all badges and incidents of slavery in the United States.").

45. See Civil Rights Cases, 109 U.S. 3, 22 (1883). The Framers of the Thirteenth Amendment expected abolition to result in the enjoyment of the "oppressed slave [of] his natural and God-given rights" and in "the political and social elevation of negroes to all the rights of white men." CONG. GLOBE, 38th Cong., 1st Sess. 2987-2990 (1864). See generally, Act of April 9, 1866, c. 31, § 1, 14 Stat. 27, re-enacted by § 18 of the Enforcement Act of 1870; Act of May 31, 1870; c. 114, § 18, 16 Stat. 140, 144, and codified in §§ 1977 and 1978 of the Revised Statutes of 1874, now 42 U.S.C. §§ 1981 and 1982 (1964).

46. *Jones v. Alfred H. Mayer Co.*, 392 U.S. 409 (1968).

47. See, e.g., *Clyatt v. U.S.* 197 U.S. 207 (1905).

48. *Jones*, 392 U.S. 409.

49. *U.S. v. Mussry*, 726 F.2d 1448 (9th Cir. 1984), *cert. denied*, 469 U.S. 855 (1984) (involuntary servitude includes psychological coercion involving one's subjugation of another's will); see *Pierce v. United States*, 146 F.2d 84 (5th Cir. 1944), *cert. denied*, 324 U.S. 873 (1945) (intimidation of women into acts of prostitution prohibited by peonage statute); see also *U.S. v. Harris*, 701 F.2d 1095, 1100 (4th Cir. 1983), *cert. denied*, 463 U.S. 1214 ("Threat of violence or confinement, backed sufficiently by deeds" suffices to subjugate human beings to the will of another in violation of the thirteenth amendment) (quoting *U.S. v. Booker*, 655 F.2d 562, 567 (4th Cir. 1981)); *U.S. v. Tibbs*, 564 F.2d 1165 (5th Cir. 1977), *cert. denied*, 435 U.S. 1007

Under the Thirteenth Amendment, Congress is empowered to secure freedom,<sup>50</sup> which may be described as the absence of restrictions, whether imposed by governments, by private individuals, or by environmental conditions.<sup>51</sup> In essence, a badge of slavery might be found in any conduct that resulted in an absence of freedom.<sup>52</sup>

Impairment of one's freedom is caused by restraints on personal autonomy, which may be separated into two related categories: internal and external.<sup>53</sup> Limits on either external or internal autonomy give rise to social inferiority and will at some point amount to subjugation. The Thirteenth Amendment clearly contemplates proscribing activities resulting in subjugation.<sup>54</sup>

In the context of genetic engineering, subjugation would result when the manufacture of a patented genotype creates inferiority in the resulting being. Subjugation of an individual with a manufactured genotype may arise from what one author terms "genetic bondage": the imposition of badges of slavery by means of genetically engineering people according to preconceived designs.<sup>55</sup> Genetic bondage may involve disabling conditions ranging from highly visible restrictions on external autonomy (e.g., genetically engineering a person to be born of low intelligence) to subtle intrusions upon internal autonomy (e.g., mass producing the same genotype throughout the population, leading to an erosion of the sense of individuality in one possessing the genotype).<sup>56</sup> Regardless

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(1978) (fear of physical harm such that the victim is afraid to leave required for finding of involuntary servitude); *United States v. Ingall*, 73 F. Supp. 76 (S.D. Cal. 1947) (retention of services under threat of prosecution for adulterous relationship). *But see United States v. Shackney*, 333 F.2d 475 (2d Cir. 1964) (conduct prohibited by involuntary servitude statute limited to slavery and peonage, i.e., use or threat of physical punishment to enforce work and use of state-imposed legal coercion to make debtor work for creditor. Threats to have employee deported held not to constitute involuntary servitude under 18 U.S.C. § 1584.).

50. *Jones v. Mayer Co.*, 392 U.S. at 443; see Note, *The "New" Thirteenth Amendment: A Preliminary Analysis*, 82 HARV. L. REV. 1294, 1307 (1969).

51. Note, *supra* note 50, at 1307.

52. Badges of slavery include "restraints upon 'those fundamental rights which are the essence of civil freedom, namely, the same right . . . to inherit, purchase, lease, sell and convey property as is enjoyed by white citizens.'" *Jones*, 392 U.S. at 441 (quoting *Civil Rights Cases*, 109 U.S. 3, 22 (1883)).

53. Internal autonomy is the individual's consciousness of himself or herself as a free agent. External autonomy is the absence of societal control over the individual's conduct. See Projects, *The Computerization of Government Files: What Impact on the Individual?* (Pt. IV), 15 UCLA L. REV. 1371, 1421-22 (1968); Note, *supra* note 8, at 515-16.

54. Restraints on internal autonomy include psychological subjugation of the type recognized in *United States v. Mussry*, 726 F.2d, 1448, 1453 (9th Cir. 1984) (coercion of individual into service by subjugation of individual's will). Restraints on external autonomy, including use of physical force and physical confinement, result in subjugation and give rise to involuntary servitude. See *United States v. Shackney*, 333 F.2d 475 (2d Cir. 1964); *United States v. Harris*, 701 F.2d 1095 (4th Cir. 1983).

55. See Note, *supra* note 8, at 517.

56. *Id.*

of the form of the subjugation, internal autonomy is impaired to the extent that the manufactured person does not have the capacity to feel free.<sup>57</sup> Moreover, an adverse impact on one's internal autonomy will have a direct and proportionate impact on external autonomy.<sup>58</sup>

A patent on a human invention can be a badge of slavery if subjugation is the direct result of the patent.<sup>59</sup> For example, the property rights conveyed in a patent may give rise to constraints in the patented individual's external or internal autonomy.<sup>60</sup> In addition, compliance with statutory requirements in filing for the patent<sup>61</sup> or practicing the patent in a particular way<sup>62</sup> may result in subjugation of the individual possessing the patented genotype. Whether patenting a genetically engineered human genotype constitutes subjugation and thus a badge of slavery may be determined by looking to the nature of the property rights granted by a patent.

The fundamental nature of an interest in property is a possessory right to exclude others from use or enjoyment of the subject matter.<sup>63</sup> The scope of the property interest may be measured by how rights in the property can be enforced. Property law has long distinguished rights in tangible personal property over which possession may be taken ("choses in possession") from rights in intangible property that can be enforced by action, but not by physical possession ("choses in action").<sup>64</sup>

A patent represents a personal property<sup>65</sup> right in an intangible thing.<sup>66</sup> Patent rights are a "species" of property<sup>67</sup> akin to "choses in

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57. *Id.* at 518.

58. *Id.*

59. *See United States v. Harris*: "[T]he statute [enacted to enforce the Thirteenth Amendment's prohibition of involuntary servitude] must be read not only to render criminal the evil that Congress sought to eradicate so long ago but as well its Twentieth Century counterpart." 701 F.2d 1095, 1100 (4th Cir. 1983) (quoting *United States v. Booker*, 655 F.2d 562, 566-67 (4th Cir. 1981)). Presumably, the Thirteenth Amendment's prohibitions would also apply to slavery and involuntary servitude's twenty-first century counterparts.

60. *See infra* notes 83-84.

61. *See infra* notes 90-91 and accompanying text.

62. *See infra* notes 75-82, 86-89 and accompanying text.

63. *See generally*, R. BROWN, *THE LAW OF PERSONAL PROPERTY* (3d ed. 1975).

64. *Id.*

65. 35 U.S.C.A. § 261 (West 1984).

66. *McClaskey v. Harbison-Walker Refractories Co.*, 46 F. Supp. 937, 938 (1942) (patent rights cannot be seized and levied, but may be subject to an in personam judgment); *cf. Stephens v. Cady*, 55 U.S. (14 How.) 528 (1852) (sale of a copperplate engraving of a map from a court's execution against the owner of the copyright did not transfer to the purchaser rights to strike off and sell copies of the map. "The copperplate engraving, like any other tangible personal property, is subject of seizure and sale, on execution, and the title passes to the purchaser, the same as if made at a private sale. But the incorporeal right, secured by the statute to the author, to multiply copies of the map, by use of the plate, being intangible, and resting altogether in grant, is not the subject of seizure or sale by means of this process . . ." *Id.* at 531); *cf. Stevens v. Gladding*, 58 U.S. (17 How.) 447, 452 (1854) (a copyright in a map and

action.”<sup>68</sup> Property rights granted under a patent are limited to those rights prescribed by Congress.<sup>69</sup> The patentee may recover damages from infringers of the patent.<sup>70</sup> And although the patentee may manufacture, use, or sell the patented product, or assign or license others to do so,<sup>71</sup> patents do not confer possessory rights in the article in which the inventor has patent rights.

Therefore, a holder of a patent in a human invention does not have rights in the physical manifestation of the patented genotype, in the trait expressed by the genetic manipulation, nor in any unaltered genotypes possessed by the recipient of the patented gene. An inventor holding a patent on a new form of human genotype would have an exclusive right only to practice the patent—that is, to make, use, or sell the patented genotype himself. The inventor would have the right only to enforce actions to exclude others from manufacturing, using, or selling the patented genotype.<sup>72</sup> Once the patented genotype is sold and implanted, the patentee impliedly licenses the recipient to use the product.<sup>73</sup>

The intangible right in a human genotype represented by a patent would not by itself impinge upon the internal or external autonomy of the person possessing that genotype. The patent holder's exercise of his right to exclude others from manufacturing, using or selling the human invention would not by itself give rise to socially imposed inferiority in patients of genetic therapy. Nor would his right to enforce actions related to the patent result in subjugation of the individual possessing that genotype manufactured under the patent. Therefore, the patent holder's rights in an invention involving a human being do not of themselves constitute badges of slavery.

## II. Unconstitutional Uses of Patented Human Inventions

Although mere ownership of patent rights in a novel human genotype would not infringe the basic constitutional freedoms of those possessing the patented gene, problems might be presented by the manner in

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ownership of the plate used to print and publish the map “are distinct subjects of property, each capable of existing and being owned and transferred, independent of the other.”)

67. See *Brown v. Duchesne*, 60 U.S. (19 How.) 183 (1856); 2 LIPSCOMB'S WALKER ON PATENTS § 8:13 (3d ed. 1985).

68. R. BROWN, *supra* note 63, at 11.

69. *Crown Die and Tool Co. v. Nye Tool and Machine Works*, 261 U.S. 24 (1923); *Gayler v. Wilder*, 51 U.S. 477 (1850). See generally 4 DELLER'S WALKER ON PATENTS, § 332, 334-37 (2d ed. 1965).

70. 35 U.S.C.A. § 284 (West 1984). When a patent has been infringed, the court may award a reasonable royalty in addition to interest and costs. In its discretion, the court also may award treble damages. *Id.*

71. *Id.* § 261.

72. See *id.* § 154.

73. See *United States v. General Electric Co.*, 272 U.S. 476 (1926).

which a patent holder decided to practice her patent. Certain practices of the patent might intrude upon fundamental rights guaranteed either explicitly or implicitly in the Constitution. The explicit constitutional right relevant to this discussion is the Thirteenth Amendment's prohibition of subjugation giving rise to badges of slavery. Genetic engineering procedures also threaten implicit guarantees such as the right to privacy and the right to procreate.

#### A. Intrusion Upon Explicit Constitutional Guarantees

Subjugation of a human being might ultimately arise from an inventor's practice of her patent. Genetic intervention that resulted in restraints on a person's autonomy might constitute a badge of slavery<sup>74</sup> and consequently a violation of the Thirteenth Amendment. Acts of subjugation arising from an inventor's practice of her patent, however, are not the same as mere ownership of a patent in a novel genotype. The PTO's prohibition on patenting human subject matter might be directed at preventing unconstitutional *uses* of patented human inventions.

##### 1. Patent Practice and the Origin of a New Species

Although subjugation would not result from granting patents for human inventions, exercising patent rights to manufacture human-animal hybrids or sub-human beings who were disabled by genetic manipulation would constitute subjugation through genetic bondage.<sup>75</sup> Through the patent holder or licensee's "control and planning [of a person's] potentiality . . . in a way that would leave the 'manufactured' person unsuitable for most . . . lifestyles and environments,"<sup>76</sup> practicing the patent could give rise to badges of slavery. Those disabled by genetic intervention would suffer severe restraints on their external autonomy. The resulting social inferiority of these beings would be a form of subjugation, so that their mere existence would constitute a form of slavery.<sup>77</sup>

Even a being manufactured with exceptional capacities could experience restraints upon external autonomy. These special capacities could give rise to a lifestyle predetermined by the being's creators.<sup>78</sup> The inability to choose the course of one's own life due to genetically engineered superior or inferior traits would deny to the affected being a fundamental freedom.

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74. See *supra* note 52.

75. See *supra* note 55 and accompanying text.

76. Note, *supra* note 8, at 520.

77. See D. RORVIK, BRAVE NEW BABY 102 (1971) (citing panel of scientists predicting use of parahumans to perform undesirable tasks).

78. Note, *supra* note 8, at 521. See A. HUXLEY, BRAVE NEW WORLD (1932) (science fiction depicting a world where societal roles are predetermined according to intellectual capacities produced by cloning).

Restraints on an individual's internal autonomy<sup>79</sup> may lead to more subtle forms of subjugation. For instance, the Sixth Circuit recently found involuntary servitude imposed by activities coming close to psychological programming.<sup>80</sup> If a thirteenth amendment violation may be found in mental coercion, it is probable that more direct control over another's thoughts and decisions imposed through genetic manipulation would certainly impinge upon that person's capacity for independent thought and action.<sup>81</sup> Therefore, programming a person's wants, values, and personality through genetic intervention would seem to violate the Thirteenth Amendment.<sup>82</sup>

## 2. *Shackles Imposed by Genetic Intervention*

One's perception that he is controlled by genetic forces programmed before birth may narrow the range of opportunities of which he will avail himself. Regardless of whether the restraints are real or fictitious, the *belief* that restraints exist may constrain internal autonomy to the point of subjugation.

An individual's knowledge that he possesses a patented genotype may create a perception that he is "less human" than non-patented individuals. If the trait is one that is commonly available in the marketplace, the individual may see himself as an article of manufacture and hence inferior to other members of society.<sup>83</sup> If one's basic nature, one's genetic identity, becomes subject to external manipulation, one's ability to conceive of oneself as a free and rational being may weaken and ultimately disappear.<sup>84</sup> Such restraints on internal autonomy could give rise to unconstitutional subjugation.

Use of gene therapy to correct blood and enzyme disorders, however, is unlikely to adversely affect internal autonomy. Corrective ge-

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79. See *supra* note 53.

80. *United States v. King*, 840 F.2d 1276 (6th Cir. 1988).

81. See Fried, *Introduction: The Need for a Philosophical Anthropology*, 48 IND. L.J. 5-27 (1973). Involuntary servitude has been found in the specific intent to subjugate the will of others so as to "render them incapable of choosing a course other than that ordered by [their master]." *United States v. King*, 840 F.2d 1276 (6th Cir. 1988) (leaders of communal cult found guilty of conspiring to hold children in involuntary servitude).

82. The *King* court recognized that agreements analogous to master/apprentice arrangements might be exempt from the Thirteenth Amendment. A contract between a parent and a genetic surgeon to implant a certain patented genotype in a fetus might represent an analogous permissible contract. Courts, however, generally review contracts concerning children to ensure they are in the child's best interest. *Id.* at 1283 (citing *Knight v. Deavers*, 259 Ark. 45, 531 S.W.2d 252 (1976)).

83. The "basis for any given legal order would be swept away by the manipulation and manufacture of human beings according to certain predetermined standards." Friedman, *Interference with Human Life: Some Jurisprudential Reflections*, 70 COLUM. L. REV. 1058, 1077 (1970).

84. Tribe, *Technology Assessment and the Fourth Discontinuity: The Limits of Instrumental Rationality*, 46 S. CAL. L. REV. 617, 648 (1974).

netic therapy contemplates use of a patented genotype as an antidote to a life-threatening condition. One possessing the patented gene would feel no less human in relation to others than would one possessing an artificial limb or a transplanted organ. Therefore, use of patented inventions in genetic surgery will not impermissibly constrain a patient's internal autonomy to the point of subjugation. Genetic manipulation for enhancement or eugenic<sup>85</sup> purposes, on the other hand, may produce inequality and lead to incursions on internal autonomy.

Wholesale manufacture and sale of the same patented genetic coding for one or several traits implanted in human beings would lessen dissimilarities among people for certain characteristics. Although paradoxical, such genetically imposed uniformity could create inequality. It has been argued, for example, that the right to an individual identity<sup>86</sup> is a deeply cherished aspect of freedom. Since innumerable possible combinations of genotypes exist, it is highly unlikely that two unrelated people would inherit identical genetic constitutions. In this context, the proclamation of the Declaration of Independence that "all men are created equal" can be interpreted as creating an equal opportunity to acquire a unique or previously undetermined genotype.<sup>87</sup>

Imposition of a predetermined genotype upon another is also likely to cause a diminution in external autonomy.<sup>88</sup> For example, if patented genotypes allow parents to choose characteristics for their children, the children may have little sense of themselves as individuals, particularly if some genetic selections are more popular than others. Conversely, those who do not inherit societally favored characteristics may be stigmatized as outcasts.

The effect on an individual's internal and external autonomy of manufacturing human genotypes would vary according to the particular manufacturing practice employed. Mass production of patented genotypes is likely to pose more of a threat to individuality and to internal and external autonomy than selective genetic manipulation. Likewise, the impact on internal autonomy from phenotypic enhancement or eugenics policies will be more significant than that caused by corrective

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85. Eugenics refers to state sponsored programs attempting to influence the genetic composition of the population. Eugenics policies may either be "positive" or "negative." "Positive eugenics" connotes a state goal to improve the community gene pool by increasing the proportion of offspring with selected genetic traits. "Negative eugenics" policies seek to reduce the occurrence of harmful phenotypes by eliminating genotypes that code for the disorder. See Vukowich, *The Dawning of the Brave New World—Legal, Ethical and Social Issues of Eugenics*, 1971 U. ILL. L.F. 189, 194. See Note, *supra* note 8, at 563. A state's negative eugenics policy might be implemented by requiring that patented genetic material which corrects a genetic defect be substituted for the defective genes in persons suffering from various inherited disorders. See Note, *supra* note 8, at 563.

86. See Note, *supra* note 8, at 507 (right to unique genotype to justify ban on cloning).

87. *Id.* at 507-08.

88. *Id.* at 518.



genetic surgery. Although protecting these interests may not justify banning all patenting of human inventions, it is sufficient to warrant the regulation of the manufacturing of human genotypes.<sup>89</sup>

### 3. Patent Disclosure

Public disclosure in a patent of a person's genetic information might well constitute a badge of slavery because those having knowledge of the phenotype expressed by patented genetic material conceivably could anticipate how one possessing the phenotype would react to certain stimuli.<sup>90</sup> The ability to predict and control responses through the selection of stimuli would limit the person's external and internal autonomy. The individual would be subjugated to those who had the ability to influence his behavior.

This analysis assumes that a particular gene's phenotypic expression can be ascertained with great accuracy from knowledge of the corresponding genotype and that specific traits give rise to highly predictable patterns of behavior. A person's phenotype, however, is not determined solely by the genetic material contained within his DNA. Environmental factors help shape the development of traits.<sup>91</sup> For example, suppose a certain genotype is created that produces a specialized predisposition to aggression in a person. Those with access to the information contained in the patent might be able to induce aggressive behavior in individuals possessing the patented genotype. The individual's behavior, however, could also be influenced by environmental factors, such as risk of danger or memories of previous encounters with police.

Because the link between behavior and DNA is anything but certain, it is unlikely that disclosure in a patent of genetic components would lead to control and subjugation of those who received patented

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89. The manner in which such regulation may be effected is discussed *infra*. See *infra* pp. 252-257.

90. Cf. Note, *supra* note 8, at 516.

91. Because a person's behavior is influenced by environment as well as by genetic makeup, the predictability of behavior based on genetic factors would be uncertain. See *Human Genetic Engineering Hearings*, *supra* note 2, at 468 (statement of Bernard D. Davis, Professor of Bacterial Physiology, Harvard University Medical School, concerning environmental and genetic influences on behavior). A controversy currently rages over which force—genetics or environment—exerts the greater influence on human behavior. See D. WOODWARD & J. WOODWARD, *CONCEPTS OF MOLECULAR GENETICS* 396 (1977). Klug and Cummings have observed, "The prevailing view is that all behavior patterns are influenced both genetically and environmentally. The genotype provides the physical and/or mental ability essential to execute the behavior and further determines the limitations of environmental influences." W. KLUG & M. CUMMINGS, *supra* note 10, at 489. See generally, D. THIESSEN, *THE GENETIC ANALYSIS OF BEHAVIOR* (1967). For an interesting examination of the writings of scientists who were active in this "nature-nurture" debate, see N. PASTORE, *THE NATURE-NURTURE CONTROVERSY* (1949) (identifying a causal relationship between sociopolitical orientation and scientific position on the nature-nurture issue).

genetic implants. If the patented gene's phenotypic expression for certain behavior cannot be predicted with confidence from information contained in the patent, then disclosure of patented genetic coding would not threaten external or internal autonomy and the patent statute's disclosure requirement could not impose a badge of slavery upon those possessing patented genotypes.

Clearly, implanting patented genes that would have the effect of enslaving individuals by "genetic bondage" would be unconstitutional. Genetic manipulation giving rise to the creation of sub-humans or human-animal hybrids impose obvious restrictions on external autonomy.<sup>92</sup> The constitutionality of incursions on internal autonomy, however, is less certain. As opposed to restraints upon external autonomy, which are imposed by outsiders, restraints on internal autonomy are a product of the subjective perception of one's own freedom. As genetic manipulation in humans becomes commonplace, patients of genetic surgery may no longer perceive themselves to be less human or less free than individuals who have not received patented genetic implants. Therefore, mild restraints on another's internal autonomy, such as disclosure of a genotype in a patent, or performing prenatal genetic surgery to implant a patented genotype, may well fall within the sphere of constitutionally permissible activity.

Permissible practices of a patent involving a human invention should be defined by the boundaries of autonomy that an individual possessing a patented genotype experiences. Although human inventions may be constitutionally the subject matter of a patent, the Constitution may narrowly confine the scope of permissible patent practices. The range of permissible practices, however, may expand as social acceptance of genetic intervention grows, influenced by the benefits that such inventions will bring to society.

## **B. Practicing a Patent and its Effect on Implicit Constitutional Rights.**

In addition to violations of the Thirteenth Amendment, the PTO may be anticipating other unconstitutional consequences of an inventor's practice of his patent. Certain fundamental rights not contained within the text of the Constitution have been found to be so basic to the Constitution's explicit scheme of civil liberties that these rights are afforded constitutional protection.<sup>93</sup> Patent statutes may infringe fundamental rights of those possessing genotypes manufactured under a patent in at

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92. See *supra* notes 75-77 and accompanying text.

93. Identifying where in the Constitution implicit rights reside is not always easy. See Lupu, *Untangling the Strands of the Fourteenth Amendment*, 77 MICH. L. REV. 981, 983-84 (1979): "Often, members of the Court agree upon the preferred status of an interest but disagree about its textual source. On occasion, members of the Court concede that an interest has no textual source, yet battle still over which strand of the fourteenth amendment protects it . . . ."

least two ways. First, as a result of sexual reproduction, a person with a patented genotype may be subject to liability for infringing the patent. Second, one's privacy interest in keeping highly personal information confidential may be infringed by a patent's disclosure of one's genetic constitution.

### *1. Patent Infringement Through Sexual Reproduction of the Genotype*

Liability for patent infringement exists regardless of intent on the part of the infringer<sup>94</sup> and even if the invention is recreated by a process other than the method employed by the inventor and disclosed in the patent.<sup>95</sup> Thus, a person having a patented genotype might be open to attack for infringing the patent if she were to reproduce the invention without license from the inventor.

Arguably, under the "doctrine of equivalents,"<sup>96</sup> sexual reproduction of a patented genotype would constitute patent infringement of the patent if the protected genetic coding were inherited by the offspring.<sup>97</sup> Consequently, people receiving patented DNA through prenatal genetic surgery would face the threat of liability upon reproduction of the patented genotype.<sup>98</sup> If the purpose of the invention were to correct a life-threatening disorder, the decision to procreate would involve harsh consequences: if the corrected genotype were not inherited, birth could result in a crippling disease; if the patented genotype were inherited, there would be a risk of suit by the inventor. Thus, patent laws might have a chilling effect on a person's decision to reproduce.

It is unlikely, however, that any court would impose infringement liability under these circumstances, since the Supreme Court has recog-

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94. "Except as otherwise provided in this title, whoever without authority makes, uses or sells any patented invention, within the United States during the term of the patent therefor, infringes the patent." 35 U.S.C.A. § 271(a) (West 1984). See *Schnadig Corp. v. Gaines Mfg. Co. Inc.*, 620 F.2d 1166 (6th Cir. 1980); *Cummins Engine Co. Inc. v. General Motors Corp.*, 299 F. Supp. 59 (D. Md. 1969), *aff'd*, 424 F.2d 1368 (4th Cir. 1970). The intent of the infringer, however, is relevant to the measure of damages. *Roller Bearing Co. of America v. Bearings, Inc.*, 328 F. Supp. 923 (E.D. Pa. 1971), *aff'd*, 475 F.2d 1399 (3rd Cir. 1971).

95. *Graver Mfg. Co. v. Linde Co.*, 339 U.S. 594 (1950).

96. The "doctrine of equivalents" is founded on the theory that "if two devices do the same work in substantially the same way, and accomplish substantially the same result, . . . even though they differ in name, form, or shape," a patentee may proceed against the producer of the device to prevent infringement of her invention. *Graver Mfg. Co. v. Linde Co.*, 339 U.S. 605, 608 (1950).

97. Couples producing the patented genotype as a result of a natural mutation, however, would not be subject to an infringement suit. In addition, such an event would likely invalidate the patent, as the invention would no longer be deemed to be statutory subject matter. See *Diamond v. Chakrabarty* 447 U.S. 303 (only living matter that is non-naturally occurring is patentable statutory subject matter).

98. Since patent protection only lasts seventeen years, persons born with patented DNA material would, in most cases, not reproduce until after the patent had expired.

nized a fundamental right of privacy in certain personal decisions.<sup>99</sup> The fundamental right of privacy has been found to encompass an individual's interest in making family planning decisions without government intrusions.<sup>100</sup> In addition, the Supreme Court has recognized procreation as "a basic liberty."<sup>101</sup> Governmental actions that abridge these interests warrant a court's strict scrutiny<sup>102</sup> and are unconstitutional absent an "extraordinary justification."<sup>103</sup>

To the extent they infringed the procreation and privacy rights of anyone entitled to constitutional protections, current patent laws would be unconstitutional. In order to overcome a presumption of unconstitutionality, the patent statute would have to be found to be narrowly tailored to promote a compelling governmental interest.<sup>104</sup>

An amendment to current patent laws, however, would eliminate the possibility of this issue arising. Analogous to an exemption under the Plant Variety Protection Act<sup>105</sup> that allows farmers to cultivate crops from seeds produced from "patented" plants, a congressional enactment could exempt parents possessing manufactured genotypes from patent infringement liability. Such an exemption would leave intact statutes protecting inventors against first generation infringement of their patents without threatening the cherished fundamental rights of persons possessing a patented genotype.

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99. See, e.g., *Roe v. Wade*, 410 U.S. 113 (1973) (reproduction decisions); *Loving v. Virginia*, 388 U.S. 1 (1967) (marriage); *Skinner v. Oklahoma*, 316 U.S. 535 (1942) (procreation); *Griswold v. Connecticut*, 381 U.S. 479 (1965) (contraception); *Prince v. Massachusetts*, 321 U.S. 158 (1944) (family relationships).

100. See *Roe v. Wade*, 410 U.S. 113 (1973) (abortion); *Griswold v. Connecticut*, 381 U.S. 479 (1965) (contraception).

101. *Skinner v. Oklahoma*, 316 U.S. 479, 541 (1965) (statute authorizing sterilization of habitual criminals held unconstitutional on equal protection grounds); but see *Buck v. Bell*, 274 U.S. 200 (1927) (sterilization statute applicable to mentally incompetent persons in state institutions upheld).

102. Strict scrutiny acknowledges that political choices burdening fundamental rights "must be subjected to close analysis in order to preserve substantive values of equality and liberty. Although strict scrutiny . . . ordinarily appears as a standard for judicial review, it may also be understood as admonishing lawmakers and regulators as well to be particularly cautious of their own purposes and premises and of the effects of their choices." L. TRIBE, *AMERICAN CONSTITUTIONAL LAW* 1451 (2d ed. 1988).

103. *Lupu, supra* note 93, at 1029-30. See, e.g., *Roe v. Wade*, 410 U.S. 113, 155 (1973)) ("Where certain 'fundamental rights' are involved, . . . regulation limiting these rights may be justified only by a 'compelling state interest,' . . . and . . . legislative enactments must be narrowly drawn to express only the legitimate state interests at stake.").

104. *Id.* at 144. See *Skinner v. Oklahoma*, 316 U.S. 535, 541 (1942).

105. 7 U.S.C.A. §§ 2321-2583 (West 1988) provides patent protection of new varieties of seeds for a period of eighteen years. Under the statute, farmers are exempt from infringement actions and from paying additional royalties for saving second generation seeds. *Id.* at § 2543.

## 2. *Patents and Privacy*

The patent statute requires a written description of an invention.<sup>106</sup> Practicing a patent to create a novel and useful genotype and implanting it in a person might infringe that person's right to privacy through the patent's public disclosure of her genetic constitution. For a human invention, the present statute appears to require public disclosure of the genetic coding for a particular trait or traits regardless of whether persons possessing the patented genotypes consent to such disclosure. Although a given individual would not be identified by name in the patent description, she would be readily identifiable if the patented genotype expressed a phenotype that was unique within the population. She would thus have a privacy interest in maintaining the confidentiality of her genetic constitution.

One element of privacy is the ability to retain and control the disclosure of personal information.<sup>107</sup> The Supreme Court has recognized a right to regulate the disclosure of personal matters.<sup>108</sup> In addition, the confidentiality of various types of sensitive information is protected by a myriad of federal and state laws governing the record-keeping activities of public employers and agencies.<sup>109</sup> The privacy right to prevent disclosure of personal information may comprise a right to control others' use of that information.<sup>110</sup> The PTO's disclosure without consent of intimate personal information<sup>111</sup> might significantly impinge on the right of privacy.

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106. 35 U.S.C.A. § 112 (West 1984).

107. See Fried, *Privacy*, 77 YALE L.J. 475 (1968).

108. See *Whalen v. Roe*, 429 U.S. 589 (1977) (striking down a law requiring doctors to disclose names of patients who obtain certain drugs); but see *Paul v. Davis*, 424 U.S. 693 (1976) (police disclosure of shoplifting arrest did not violate suspect's right of privacy).

109. See *Detroit Edison Company v. National Labor Relations Board*, 440 U.S. 301 (1979) (privacy interest as grounds for restricting disclosure without consent of employee's test scores to union). The *Detroit Edison* court cited the following as examples of such legislation: Privacy Act of 1974, 5 U.S.C. § 552A (written consent required for disclosure of information in individual records); COLO. REV. STAT. § 24-72-204(3)(a) (1973) (regulating disclosure of medical, psychological, and scholastic achievement data in public records); IOWA CODE ANN. § 68A.7(10)-(11) (West 1973) (regulating disclosure of personal information in public employee records); N.Y. PUB. OFF. LAW § 89(2)(b)(i)-(c)(ii) (McKinney Supp. 1978) (disapproving release of employment and medical information in public records without consent).

110. See *United States v. Hooker Chemical & Plastics Corp.*, 112 F.R.D. 325 (W.D.N.Y. 1986) (health information of Love Canal area residents obtained during state-conducted health emergency studies was confidential and not subject to disclosure).

111. "[A] genetic profile is likely to be a permanent fixture of one's biological legacy." Lappe, *The Limits of Genetic Inquiry*, HASTINGS CENTER REP. 7 (Aug. 1987). Genetic counselors have discovered that many persons affected with genetic disorders perceive genetic information as more personal and more revealing than medical history or credit history. Leonard, Chase, and Childs, *Genetic Counseling: A Consumer's View*, 287 NEW ENG. J. MED. 433 (1972).

Judicial recognition of an interest in maintaining the confidentiality of health records and hereditary information might also include protection of genetic data from disclosure without the consent of the individual involved.<sup>112</sup> The Supreme Court, however, is unlikely to render patenting of human beings unconstitutional on the basis of a violation of the right of privacy by the patent statute's disclosure requirement. Such a ruling would be an overreaction to the violation of a right that the Court has recognized only implicitly. Yet incursions on privacy interests may justify striking down the patent disclosure statute as unconstitutional. Mandatory public disclosure of a person's genetic constitution in a patent would seem to infringe a protected privacy interest in that person's control over another's use of personal information.

An exception to the patent statute could provide sufficient protection against the disclosure of intimate genetic information in patents. An exception similar to that provided under the Freedom of Information Act (FOIA)<sup>113</sup> might be formulated. Under the FOIA exemption, information involving medical files, the disclosure of which would constitute "a clearly unwarranted invasion of personal privacy," may be withheld from disclosure.<sup>114</sup> The exemption is intended to protect individuals from a "wide range of embarrassing disclosures,"<sup>115</sup> including information relating to "marital status, legitimacy of children, identity of fathers of children, [and] medical condition . . . ."<sup>116</sup>

Similarly, an exemption to the patent statute's disclosure requirement could provide for release of personal information relating to an individual's patented genotype only upon a request made to the PTO commissioner. Disclosure of the information would be justified only when the commissioner determines that the private concerns seeking the information outweigh the patented gene recipient's interest in keeping the information confidential.<sup>117</sup> An exemption preventing indiscriminate disclosure of an individual's genetic makeup would safeguard the confidentiality of personal information, a fundamental right of privacy.

### 3. Summary

Although ownership of patent rights in genetically altered human beings might be constitutional, the exercise of a patentee's rights could

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112. *Cf. U.S. v. Hooker Chemical & Plastics Corp.*, 112 F.R.D. 325 (W.D.N.Y. 1986).

113. 5 U.S.C.A. § 552 (West 1977). FOIA mandates a policy of broad disclosure by governments when production is properly requested. When a request is made, an agency may withhold a document, or portions thereof, only if the information falls within one of nine statutory exemptions.

114. *Id.* § 552(b)(6).

115. *Board of Trade v. Commodity Futures Trading Commission*, 627 F.2d 392, 399 (D.C. Cir. 1980); *Fitzgibbon v. CIA*, 578 F. Supp. 704 (D.D.C. 1983).

116. 627 F.2d at 399.

117. *Cf. Rural Housing Alliance v. USDA*, 498 F.2d 73, 77 (D.C. Cir. 1974).

infringe protected civil liberties. If "manufacture" of patented human inventions resulted in only subtle restraints on the patented subject's internal autonomy, the inventor's practice of her invention would likely be found constitutional. But if patent practice resulted in extreme forms of subjugation, such as that involved in the creation of animal-human hybrids or sub-human life forms, the practice would likely be unconstitutional.

For instance, although the patent statute gives a patentee the right to exclude others from manufacturing her invention, strict enforcement of that right could infringe the "manufactured" person's constitutionally protected right to procreate. Narrow tailoring of the patent statute would be necessary in order to preserve its constitutionality. This could be achieved by amending the statute to exclude infringement claims against patented human beings whose patented genotypes were reproduced in offspring.

The "manufacturing" of patented human genotypes would also threaten the privacy interests of individuals who were recipients of the genetic implants. Public disclosure of a person's genetic constitution in a patent would compromise the patented individual's interest in maintaining the confidentiality of personal information. An amendment to the present patent disclosure statute, similar to an exemption provided under the Freedom of Information Act, would protect this privacy interest.

### III. Unconstitutional Consequences of the Patent

Although the uses to which an inventor put his patent might raise constitutional issues, still other problems are foreseeable. Allowing products of human genetic engineering to be patented might foster constitutional violations by persons other than the inventor.

#### A. Private Actions

Discrimination against those with manufactured genotypes would be particularly acute if the patented genetic material expressed a unique, observable phenotype or trait. Alternatively, individuals without such genetic implants might be discriminated against for *not* possessing certain patented genotypes deemed to be superior. As such, the PTO's prohibition may be intended to prevent unconstitutional discrimination arising from the dissemination of certain patented human genes.

The workplace is one area where discrimination based on genetic factors — race and sex — has occurred in the past and will likely occur again.<sup>118</sup> The language of Title VII suggests that the Act might be inter-

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118. Title VII of the Civil Rights Act of 1964 prohibits discrimination in employment practices based on "race, color, religion, sex, or national origin." 21 U.S.C.A. §§ 2000, 2000e-

puted to include discrimination on the basis of genetic makeup.<sup>119</sup> If so, an employer's refusal to hire a person because she possesses a patented genotype would violate Title VII and might provide an avenue for redressing injuries suffered as a result of the discrimination.

Conversely, a recipient of a patented genotype that provided certain biological benefits might be given hiring preference over a person without the patented genotype. Suppose that a phenotype provided superior resistance to the toxicity of certain environmental agents.<sup>120</sup> Employers might prefer to fill certain jobs with individuals who have this patented genotype. Discrimination in favor of patented individuals may be justified by the employer's interest in employee safety.<sup>121</sup> Nevertheless, preferences create class distinctions between persons possessing patented and non-patented genes.

## B. State Actions

Similarly, discriminatory state actions may result from allowing human inventions to be patented. The availability of surgical procedures for implanting patented genes may inspire lawmakers to require the production and dissemination of patented genotypes that yield certain desired characteristics. Although a law requiring correction of genetic defects in afflicted individuals would likely pass constitutional scrutiny,<sup>122</sup> legislation mandating the manufacture of individuals with certain state-sponsored genetic coding would compromise constitutional guarantees, including privacy rights to be free from governmental intrusion, thirteenth amendment protections against subjugation, and the prohibi-

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2 (West 1964). This prohibition applies to employers with twenty-five or more employees. See, e.g., *Phillips v. Martin Marietta Corp.*, 400 U.S. 542 (1971) (sex discrimination).

119. *Saint Francis College v. Al-Khazraji*, 107 S.Ct. 2002 (1987), held that racial discrimination under 42 U.S.C. § 1981 includes "discrimination against an individual because he or she is generally part of an ethnically and physiognomically distinctive sub-grouping of *Homo sapiens*." Minimum requirements for height and weight, which are genetically determined characteristics, have been found to have a discriminatory impact on women job applicants. *Dothard v. Rawlinson*, 433 U.S. 321 (1977).

120. Some people have a deficiency in the enzyme glucose-6-phosphate dehydrogenase (G-6-PD) caused by a variation in the form of a single gene. The deficiency is usually harmless, but if affected individuals take certain medications for treatment of malaria, they may suffer from acute anemia. People with G-6-PD deficiency may be at increased risk of disease in workplaces where they are exposed to chemicals similar to the antimalaria drugs. U.S. CONGRESS, OFFICE OF TECHNOLOGY ASSESSMENT, *THE ROLE OF GENETIC TESTING IN THE PREVENTION OF OCCUPATIONAL DISEASE* (SUMMARY) 9 (1983).

121. A "bona fide occupational qualification" establishes an exception to Title VII's general prohibition against discrimination. An employer who discriminates in hiring on the basis of a characteristic must demonstrate a factual basis for believing that the excluded group of persons would be unable to perform the duties of the job safely and efficiently. *Weeks v. Southern Bell Telephone & Telegraph Co.*, 408 F.2d 228 (5th Cir. 1969).

122. See *infra* notes 136-140 and accompanying text.



tion of creating a class of superior citizenry.<sup>123</sup>

The Fourteenth Amendment's Equal Protection Clause<sup>124</sup> prohibits discriminatory state actions.<sup>125</sup> Legislation that treats people differently on the basis of a "suspect" classification must overcome a presumption that it is unconstitutional.<sup>126</sup> A classification is suspect if the distinction is based on an immutable characteristic.<sup>127</sup> Invidious discrimination against a "discrete and insular minority" in need of "extraordinary protection from the majoritarian political process" warrants strict judicial scrutiny of the legislation.<sup>128</sup> Disparate treatment may be justified if the classification is necessary to further a compelling government interest.<sup>129</sup>

A "negative eugenics" statute, requiring replacement of defective genes with a patented genotype to cure an inherited disease, would differentiate between people who possess the genetic defect and those who do not. Since inherited characteristics are immutable, classification on the basis of genetic constitution could be characterized as "suspect," and thus be subject to strict scrutiny, the standard for suspect classifications. But, since negative eugenics policies seek not to impose a burden but to eliminate the debilitating effects of genetic disorders, a state might be able to show a compelling interest for such a classification.

Alternatively, a court might find a more lenient standard warranted. A law having a discriminatory effect in mandating correction of genetic defects might be subject to an intermediate standard of review, the same as that for other laws that classify people on the basis of genetically-influenced characteristics, namely gender. Such a standard would require that negative eugenics laws be "substantially related" to an "important" governmental interest.<sup>130</sup>

Three state interests might be raised in an attempt to justify a statute mandating correction of defective genetic material.<sup>131</sup> One would be the

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123. See *infra* notes 141-149 and accompanying text.

124. U.S. CONST. amend. XIV, § 1.

125. The Fifth Amendment's Due Process Clause has been interpreted to provide the same protection against discrimination imposed by federal laws. U.S. CONST. amend. V. See e.g. *Bolling v. Sharpe*, 347 U.S. 497 (1954) (public school segregation in District of Columbia held violative of due process).

126. See *Korematsu v. United States*, 323 U.S. 214, 216 (1944).

127. See *Loving v. Virginia*, 388 U.S. 1 (1967) (race); *Oyama v. California*, 332 U.S. 633 (1948) (national origin); but see *Mathews v. Lucas*, 427 U.S. 495 (1976) (illegitimacy held not to constitute a suspect class).

128. *United States v. Carolene Products Co.*, 304 U.S. 144, 152 n.4 (1938). The Fourteenth Amendment requires a very heavy burden of justification for state statutes drawn according to race. *Loving v. Virginia*, 338 U.S. 1 (1967). See J. NOWAK, R. ROTUNDA & J. N. YOUNG, *CONSTITUTIONAL LAW* 531 (3d ed. 1986) [hereinafter NOWAK].

129. *Id.* at 580.

130. See *Craig v. Boren*, 429 U.S. 190, 197 (1976).

131. Kass, *Making Babies—The New Biology and the Old Morality*, 26 PUB. INT. 18, 39-45 (1972). See also Note, *supra* note 8, at 566.

elimination of deleterious genes from the gene pool.<sup>132</sup> Practiced on a vast scale, prenatal genetic surgery could reduce the total number of harmful genes in the population,<sup>133</sup> thereby decreasing the frequency with which fatal diseases occur. A second state interest would be to reduce the financial burdens on society of caring for individuals afflicted with genetic diseases.<sup>134</sup> Third would be the state's interest in preventing pain and suffering experienced by victims of such diseases.<sup>135</sup>

A negative eugenics law would serve these three state interests. The Supreme Court has identified public health as "an important and legitimate interest."<sup>136</sup> A legislature can enact "reasonable regulations" to protect public health and safety, including a compulsory vaccination program to prevent the spread of communicable diseases.<sup>137</sup> Likewise, a government's public health powers may be exercised in line with its interest to protect future generations from the spread of disease through genetic processes.<sup>138</sup> Correction of genetic defects in fetuses could help

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132. "Three generations of imbeciles are enough." *Buck v. Bell*, 274 U.S. 200, 207 (1927) (sterilization of institutionalized mentally retarded woman who was "the daughter of a feeble minded mother in the same institution, and the mother of an illegitimate feeble minded child," found not to violate due process).

133. *SPLICING LIFE*, *supra* note 31, at 46. But see *Human Genetic Engineering Hearings*, *supra* note 2, at 187 (testimony of Professor Alexander Capron, Executive Director, President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research): "[W]hat are regarded as genetic diseases today might be needed because of some advantage they would give in other circumstances."

134. See *Buck v. Bell*, 274 U.S. at 207: "It would be strange if [the state] could not call upon those who already sap the strength of the state for these lesser sacrifices (sterilization), often not felt to be such by those concerned, in order to prevent our being swamped with incompetence."

135. Sterilization laws also implicate the interest in preventing pain and suffering. *Buck v. Bell*, 274 U.S. at 207: "It is better for all the world, if instead of waiting . . . to let [offspring] starve for their imbecility, society can prevent those who are manifestly unfit from continuing their kind." Compare *Skinner v. Oklahoma*, 316 U.S. 535, 545 (1941) (Stone, C.J., concurring) ("the state may protect itself from . . . inheritable tendencies of the individual which are injurious to society"), with *Perez v. Sharp*, 32 Cal. 2d 711, 726, 198 P.2d 17, 26 (1948) ("the state 'may properly protect itself as well as the children by taking steps which will prevent the birth of offspring. . . .'").

136. *Roe v. Wade*, 410 U.S. 113, 162 (1973).

137. *Jacobson v. Massachusetts*, 197 U.S. 11, 29 (1985) (small pox).

138. *Buck v. Bell*, 274 U.S. at 207; *Jacobson v. Massachusetts*, 197 U.S. 11, 25 (1905). Governmental imposition of mandatory medical treatment runs counter to the privacy rights of individuals who refuse such treatment. But when the safety of innocent third persons is at stake, the state's interest is compelling and individual privacy interests are sacrificed. Compare *In re Quinlan*, 355 A.2d 647 (N.J. 1976) (right of privacy extended to termination of life-sustaining medical care) and *Rogers v. Okin*, 390 Mass. 489, 458 N.E.2d 308 (1983) (privacy right of non-institutionalized mental patients to refuse anti-psychotic drugs) with *Jefferson v. Griffen Spalding Co. Hospital*, 247 Ga. 86, 274 S.E.2d 457 (1981) (court order upheld authorizing physicians to perform cesarean section and give patient blood transfusions against her will). It seems that those who consent to sterilization, however, may be entitled to refuse treatment for their genetic disorders.

save pregnancies and alleviate the substantial burdens of care on society that the birth of a genetically defective child might impose.<sup>139</sup> As an additional safeguard, mandatory prenatal genetic surgery could be limited to circumstances where the likelihood of a particular disease and the potential for pain and suffering are great.<sup>140</sup> So limited, the purposes served by a negative eugenics statute might be deemed compelling. At a minimum, such a law would likely pass muster under an intermediate standard of review.

On the other hand, a positive eugenics law expressing state preferences for certain traits would be more vulnerable to constitutional attack. According to one commentator, "improvement of the genetic makeup of the community differs greatly in degree, if not in kind, from the . . . interest in preventing extreme suffering that justifies negative eugenics."<sup>141</sup> A positive eugenics law would impermissibly burden those who do not possess the characteristic endorsed by the government.<sup>142</sup> Such a law would also interfere with the fundamental right to be free from government intrusions in one's personal life.<sup>143</sup> Under strict scrutiny, the state would have the burden of showing the eugenics statute was "necessary to promote a compelling governmental interest."<sup>144</sup> Improving the vigor of the gene pool might be a desirable goal, but such a purpose would represent a state interest that is speculative rather than compelling. The benefits to be derived from a positive eugenics law are not likely to overcome the severe burden that discrimination and intrusion on personal privacy would impose on the state's citizenry.

Another problem with a law promoting positive eugenics is the potential for creating a generation with superior traits. It has been asserted that such a result might be equivalent to the creation of a superior noble class,<sup>145</sup> which would be prohibited under the Constitution's Nobility Clause.<sup>146</sup> The Supreme Court has expressed repugnance toward the de-

139. Note, *Eugenic Sterilization—A Scientific Analysis*, 46 DENV. L.J. 631, 650 (1969).

140. Cf. SPlicing LIFE, *supra* note 31, at 66 (involuntary blood transfusions of pregnant women have been ordered by courts when physicians conclude it is necessary to prevent serious harm to fetuses).

141. Note, *supra* note 8, at 579; see Gustafson, *Genetic Counselling and the Uses of Genetic Knowledge—An Ethical Overview*, ETHICAL ISSUES IN HUMAN GENETICS 101 (1973).

142. See *Keyes v. School Dist. No. 1*, 609 F. Supp. 1491, 1498 (D. Colo. 1985) ("[T]he Constitution requires . . . that the government must not itself act as an agent of predestination in association with any immutable characteristic of birth.")

143. See NOWAK, *supra* note 128, at 685. Cf. *Meyer v. Nebraska*, 262 U.S. 390 (1923) (statute prohibiting grade schools from teaching in language other than English struck down); *Pierce v. Society of Sisters*, 268 U.S. 510 (1925) (statute requiring students to attend public school instead of private school held to violate due process).

144. *Shapiro v. Thompson*, 394 U.S. 618, 634 (1969).

145. See Note, *supra* note 8, at 579-82.

146. "No Title of Nobility shall be granted by the United States . . ." U.S. CONST. art. I, § 9, cl. 8. "No State shall . . . grant any Title of Nobility." U.S. CONST. art. I, § 10, cl. 1. At least one court has observed, "The rationale behind prohibition against any title of nobility . . .

velopment of a superior class of people.<sup>147</sup> State action promoting certain genetic traits would infringe thirteenth amendment protections. A state's preference for some genotypes would necessarily make other genotypes officially undesirable; those with undesirable genotypes would be subjugated to those with government-sponsored genotypes. Thus, unpatented genotypes would represent a badge of slavery.<sup>148</sup> Notwithstanding the unconstitutionality of such a law, the ominous tone of Professor Stich's remarks regarding human genetic engineering during his testimony before Congress would make any legislator think twice before enacting a positive eugenics statute: "[T]hose who are unwilling or unable to take advantage of the new technology may find that their offspring have been condemned to a sort of second class citizenship in a world where what had been within the range of the normal gradually slips into the domain of the subnormal."<sup>149</sup>

### C. Summary

The consequences of allowing human beings to be patented may include unconstitutional state and private actions. The ability to produce humans according to specification, and the commercial availability of such patented products, contemplates the development of preferences for individuals possessing certain genetic characteristics. Such preferences may be expressed by private parties in the form of discriminatory employment practices. Alternatively, enactment of eugenics legislation would demonstrate state preference for certain genotypes over others. Many such actions would be unconstitutional.

## IV. Constitutionality as a Condition Precedent to Patentability

Patent law is at a crossroads. Constitutional authorization for patent rights in human inventions intersects with constitutional protection of civil liberties. The PTO's unexplained contention that patents on human beings are unconstitutional may be based on the unconstitutionality of foreseeable patent practices or of anticipated private and state actions arising from implants of patented genes. If so, the PTO has

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equally would permit the United States from attaching any badge of ignobility to a citizen at birth." *Eskra v. Morton*, 524 F.2d 9, 13 n.8 (7th Cir. 1975).

147. The Court in *Meyer v. Nebraska* stated, "[T]he state may do much, go very far, indeed, in order to improve the quality of its citizens, physically, mentally, [and] morally, . . . but the individual has certain fundamental rights which must be respected." 262 U.S. 390, 401-02 (1923) (striking down a statute prohibiting teaching of foreign languages to school children on due process grounds).

148. *Cf.* Note, *supra* note 8, at 581 (arguing that to deny one the opportunity to clone oneself may constitute a "badge of slavery" where genotypic inferiority would deny a right to reproduce while an elite group is granted the right to clonal reproduction).

149. *Human Genetic Engineering Hearings*, *supra* note 2, at 537 (testimony of Stephen Stich, professor of philosophy, University of Maryland).

constructively imposed a new requirement for protecting inventions under United States patent laws: all uses of an invention must be constitutional.

Article I of the Constitution gives Congress broad power to legislate "[t]o promote the Progress of . . . useful Arts, by securing for limited Times to . . . Inventors the exclusive Right to their Discoveries."<sup>150</sup> The Patent Act of 1952<sup>151</sup> is Congress' most recent enactment pursuant to this grant of authority.

In contrast, the PTO has only statutory authority to apply the legislative scheme enacted by Congress.<sup>152</sup> The PTO is neither empowered nor competent to make constitutional determinations. To the extent the PTO rules on a patent's constitutionality, it oversteps its authority and frustrates the constitutional standard set forth in Article I.

### A. Legislative History of United States Patent Laws

The Patent Act of 1793, authored by Thomas Jefferson, "embodied Jefferson's philosophy that 'ingenuity should receive a liberal encouragement.'"<sup>153</sup> In *Diamond v. Chakrabarty*<sup>154</sup> the court declared patentable subject matter to "include anything under the sun that is made by man."<sup>155</sup> The legislative history of patent laws supports the Court's interpretation.<sup>156</sup> Congress employed broad general language in drafting 35 U.S.C. § 101 precisely because inventions are often unforeseeable.<sup>157</sup> To effectuate its constitutional directive, Congress contemplated that patent laws should be given broad interpretation.<sup>158</sup>

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150. U.S. CONST. art. I, § 8, cl. 8. See *Diamond v. Chakrabarty*, 447 U.S. 303, 307 (1980).

151. 35 U.S.C.A. §§ 1-272 (West 1984).

152. *Graham v. John Deere Co.*, 383 U.S. 1, 6 (1966).

153. *Chakrabarty*, 447 U.S. at 308-9 (citing WRITINGS OF THOMAS JEFFERSON at 75-76 (Washington ed. 1871)); see *Graham*, 383 U.S. at 7-10.

154. 447 U.S. 303 (1980). *Chakrabarty's* patent contained a claim to a human-made, genetically engineered bacterium capable of breaking down multiple components of crude oil. *Id.* at 305. *Chakrabarty's* invention met the statutory requirements of novelty, utility and non-obviousness, but was rejected by the PTO and the patent office board of appeals on the basis that living things are not patentable subject matter. *Id.* at 306. The Supreme Court, construing the patent statute broadly, concluded that 35 U.S.C. § 101 includes living things. *Id.* at 314.

155. *Id.* at 309 (quoting S. REP. NO. 1979, 82d Cong., 2d Sess., 5 (1952); H.R. REP. NO. 1923, 82d Cong., 2d Sess., 6 (1952)).

156. See S. REP. NO. 1979, 82d Cong., 2d Sess., 5 (1952); H.R. REP. NO. 1923, 82d Cong., 2d Sess., 6 (1952); see also Patent Law Codification and Revision Hearings on H.R. 3760 before Subcommittee No. 3 of the House Committee on the Judiciary, 82d Cong., 1st Sess. 37 (1951) (testimony of P. J. Federico).

157. *Chakrabarty*, 447 U.S. at 316 n.10 (listing unforeseen patented inventions: telegraph, telephone, electric lamp, airplane, transistor, atomic reactor, laser).

158. *Id.* at 308.

## B. Patentability of Inventions Used for Illegal Purposes<sup>159</sup>

A patent in an invention grants the inventor exclusive rights in her invention for a limited time, subject to state and federal law.<sup>160</sup> Prohibiting the use of a patented article goes to the use of the article, not to the grant of the patent.<sup>161</sup> A patent is not invalid because it may be possible to put the article to use for an illegal purpose. If a device may be legally employed and is "normally and naturally adaptive to a lawful use, the patent . . . will not be held invalid as against public policy."<sup>162</sup>

Congress' grant of constitutional authority to enact patent laws, however, is limited to "the promotion of the 'useful arts.'"<sup>163</sup> Although contemplated illegal or immoral uses of an invention do not render the invention unpatentable, an article may not meet the statutory usefulness requirement if the only use to which an invention can be put is an illegal one.<sup>164</sup> But if an invention can be put to any lawful purpose, the usefulness requirement will be met and the article will be patentable. The same conclusion should obtain if an invention has uses that are constitutional: the usefulness requirement will be satisfied and the invention will be patentable.

A person who commits an illegal act with a patented invention is subject to legal sanctions. Similarly, a person who suffers a constitutional injury as a result of a patented invention's use has a claim against those who inflicted the harm. If the injury results from practice of the patent, the plaintiff may seek relief from the inventor or her licensees. If an inventor's practice of a patent resulted in subjugation and violated the Thirteenth Amendment, she would be subject to prosecution under federal peonage statutes.<sup>165</sup>

If the injury results from actions of third parties such as a private individual or the government, the plaintiff may seek relief from that third party. Thus an employer who hired an employee solely on the basis of a phenotype expressed by a patented genotype might be liable, under Title

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159. Illegality and unconstitutionality do not completely overlap. Analysis of the effect of an invention's illegal applications, however, is useful by analogy in determining patentability of human inventions whose potential uses would violate a provision of the Constitution.

160. *Bloomer v. McQuewan*, 55 U.S. 539, 549 (1852); *United Shoe Machinery v. United States*, 258 U.S. 451, 463 (1921); and see *Patterson v. Kentucky*, 97 U.S. 501, 503 (1878).

161. *Fuller v. Berger*, 120 F. 274, 279 (7th Cir. 1903).

162. *Koppe v. Burnstingle*, 29 F.2d 923, 925 (D. R.I. 1929).

163. *Graham v. John Deere Co.*, 383 U.S. 1, 5 (1966).

164. The cases involve patented inventions used as gambling devices in contravention of local law. See *Fuller v. Berger*, 120 F. 274 (7th Cir. 1903); *Koppe v. Burnstingle*, 29 F.2d 923, 925 (D.R.I. 1929); and see 35 U.S.C.A. § 101 (West 1984).

165. 18 U.S.C. § 1581 provides that one who is found guilty of holding a person in peonage shall be fined a maximum of \$5000 and is subject to up to five years imprisonment. 18 U.S.C.A. § 1581 (West 1984). A patentee of a human invention might also come under the provisions of 18 U.S.C. § 1584, and would be subject to the same penalties if the patented genes expressed phenotypes subjugating those persons into whom the genotype was implanted.

VII, to those without the genotype who weren't hired. Or a plaintiff might seek to enjoin the practice of inserting certain patented genotypes in fetuses pursuant to a state's positive eugenics statute.

Remedies exist at law for unconstitutional uses of patented inventions, just as remedies exist for an invention's illegal uses. Legal remedies provide a sufficient disincentive for employing a patented invention to unconstitutional ends. In addition, the usefulness requirement presents an impediment to patenting inventions whose uses have exclusively unconstitutional effects.

Human inventions will have useful and lawful applications. Selection of physical or mental characteristics by parents for their offspring may be advantageous for survival and success. For example, parents might choose a patented genotype for their child that would produce a phenotype providing greater immunity to infection and disease. Yet the potential for unconstitutional uses of a human invention remains. Commercial availability of a useful human genotype may induce a government authority to require that all fetuses receive implants of the patented gene. Thus a human invention's usefulness might come at the expense of potential unconstitutional consequences. Determining the patentability of human inventions might best be accomplished by balancing the utility of the invention against illegal or unconstitutional effects that are likely to develop. Since the PTO lacks the competence to assess the significance of the constitutional impact human inventions might have, a balancing of utility and effects should be made by courts or by Congress.<sup>166</sup> Not only does the PTO lack competence to make such constitutional determinations, but it also lacks the authority to impose new requirements for the patentability of human inventions.

### C. The PTO's Authority to Bar Patents on Human Inventions

The Patent and Trademark Office is vested with the duty to grant and issue patents.<sup>167</sup> This duty is limited to examining patent applications "to determine if they meet requirements of law for the issuance of patents . . . ."<sup>168</sup> In addition, the Commissioner of the PTO may establish regulations for PTO proceedings,<sup>169</sup> and may perform functions that are "necessary and proper" in the exercise of the authority delegated to his office.<sup>170</sup> The Commissioner's responsibilities also include establishing policies and regulations pertaining to the administration of patent laws; the Commissioner plays a "key role in intellectual property issues

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166. See *infra* notes 183-196 and accompanying text.

167. 35 U.S.C.A. § 6 (West 1984).

168. 48 Fed. Reg. 14,735 (1983).

169. *Id.*

170. *Id.*

confronting the nation.”<sup>171</sup> This role, however, neither encompasses making laws that define the scope of patent protection to which broad categories of inventions are entitled nor determines issues of constitutional law arising from the use of patented inventions. Only Congress has the power to enact laws pertaining to patents,<sup>172</sup> and only the courts may determine the constitutionality of actions conducted under these laws.<sup>173</sup>

All of the conditions of patentability are set out in the 1952 Patent Act.<sup>174</sup> In its policy to deny patents on human inventions, the PTO appears to be imposing an additional requirement of “constitutional use” on the patentability of inventions.<sup>175</sup> But nowhere within Title 35 is there a requirement that all the uses of an invention must be constitutional.<sup>176</sup> A human invention that meets the statutory requirements of novelty, nonobviousness and utility is patentable.<sup>177</sup> To the extent that the PTO rejects patent applications on the basis that the inventions will produce a constitutional injury, the PTO fails to fulfill its duties.

Even if the PTO had the authority to enact a rule that inventions must not have unconstitutional uses, the PTO is not competent to assess the constitutionality of a human invention’s uses. Nor is the PTO competent to resolve the difficult moral and ethical problems that invention of artificially engineered human genotypes will pose.<sup>178</sup> Therefore, the PTO’s prohibition on patenting of human inventions on the grounds of

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171. *Id.*

172. U.S. CONST. art I, § 8, para. 8.

173. *Marbury v. Madison*, 1 Cranch. 137 (1803).

174. Where Congress is silent, the Supreme Court has found implied limitations and conditions. *United States v. Dubilier Condenser Corp.*, 289 U.S. 178, 199 (1933): “In choosing such expansive terms as ‘manufacture’ and ‘composition of matter,’ modified by the comprehensive ‘any,’ Congress . . . contemplated that the patent laws would be given wide scope.” *Diamond v. Chakrabarty*, 447 U.S. 303, 308 (1980).

175. In *Graham v. John Deere Co.* the Court articulated the function of the PTO, which did *not* include formulating new conditions of patentability: “It is the duty of the Commissioner of Patents and of the courts in the administration of the patent system to give effect to the constitutional standard by appropriate application, in each case, of the statutory scheme of the Congress.” 383 U.S. 1, 6 (1966).

176. At least one court has determined that “[u]nder 35 U.S.C. § 102 an applicant is ‘entitled to a patent unless’ it is shown that one or another of the prohibitory provisions therein . . . applies.” *In re Stempel*, 241 F.2d 755, 759-60 (C.C.P.A. 1957).

177. Living biological material that is the product of human genetic intervention is patentable subject matter. *Chakrabarty*, 447 U.S. 303. Whether the living matter is of human origin is irrelevant.

178. If the Supreme Court is not competent to resolve such issues, then the PTO is not either. Chief Justice Burger, writing for the Court in *Chakrabarty*, referred to the “gruesome parade of horrors” of pollution, disease, the risk of loss of genetic diversity, and the potential for depreciating the value of human life posed by genetic research and technological development, and concluded that the Court is “without competence to entertain these arguments—either to brush them aside . . . or to act on them.” 447 U.S. at 316-17. Politically sensitive issues such as these are traditionally left to the legislature to resolve.



unconstitutionality not only ignores the meaning of the patent laws it administers, but also disregards limits on its power as an administrative agency.

#### D. Summary

In order to be patentable, an invention must meet the statutory requirements enacted by Congress. One of these requirements is usefulness. Although an invention that can be used only for illegal purposes will not meet the usefulness requirement, an invention is patentable if it can be put to any lawful purpose. Certain practices of a patent on a human invention and certain private and state actions arising from allowing human inventions to be patented pose constitutional problems. The potential frequency and severity of such unconstitutional effects of the patent may reduce the invention's utility, which may render the invention unpatentable.

Certain human inventions capable of being employed in a manner having unconstitutional effects, however, would not meet the usefulness threshold for patents. New human life forms that meet the statutory requirements, including usefulness, are patentable. But because the PTO lacks competence to make determinations of constitutional law, the PTO is unable to assess whether human inventions meet the usefulness standard. On the other hand, if the PTO's policy to prohibit patents on human inventions imposes an additional requirement on patentability, the PTO has exceeded its powers as an administrative agency.

### V. Regulation

The issues involved in deciding how life can or should be altered and the uses to which genetically altered products can be put are "well beyond the competence or authority of the Patent Office."<sup>179</sup> In its prohibition of patents on human inventions, the PTO was probably attempting to forestall problems that would ultimately arise. Although granting patent rights in human genotypes does not in itself violate provisions of the Constitution, the potential for abuse of human inventions are matters of public concern.<sup>180</sup> To ensure that fundamental constitutional rights continue to be protected while encouraging the development of patentable

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179. *Id.* at 22; see *Patent Hearings*, *supra* note 15 at 182 (testimony of Professor Robert P. Merges, Columbia Law School): "The patent system is not normally the proper place to conduct technology assessment." See also H.R. 1827, amend. no. 245, 100th Cong., 1st Sess. (proposal to bar the PTO from expending funds during fiscal year 1987 for purpose of granting patents on genetically altered animals); 133 CONG. REC. S7268 (daily ed. May 28, 1987) ("[S]uch a monumental decision about the fate of animal life should not be left only to the U.S. Patent Office.") (statement of Sen. Hatfield). The amendment was ultimately deleted from the Senate appropriations bill.

180. A National Science Foundation survey indicates that almost two-thirds of the public believe studies in creating new life forms should not be pursued. Walsh, *Public Attitude To-*

inventions, regulations should forbid unconstitutional practices in the use, manufacture, and sale of human products of genetic engineering. To be fully effective, such regulation must also provide for oversight to prevent the development of unconstitutional state and private actions that might arise out of the commercial availability of patented human inventions.

In 1982 Professor Alexander Capron, Executive Director of the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, testified before a House Subcommittee on the ethical and social issues raised by genetic engineering. He stated that "no legal or regulatory prohibition" exists on "creating an actual being with partially human characteristics."<sup>181</sup> Other commentators have also expressed concern over how the creation of new life forms will be controlled; one of them averred that "[t]he PTO is the only public agency currently discussing issues of what novel life forms may be created and manufactured."<sup>182</sup> Certainly there is room for wider participation in this important area of policy-making.

Outside of the PTO, regulation of patented human genetic engineering technology and its products might occur at three different levels: judicial assessment of the constitutionality of various uses of patented products; legislative control over patented human inventions and their uses; and administrative regulation of the manufacture of patented human genetic material.

#### A. Judicial Review of the Use of Patented Human Genotypes

While review of acts of Congress is clearly a judicial function,<sup>183</sup> the Supreme Court is unlikely to rule that patents on human beings are per se unconstitutional.<sup>184</sup> In light of the irreversibility and the potentially ubiquitous impact of genetic engineering, "courts lack the sophisticated research tools for solving the relatively novel problems posed and thus should give great weight to legislative evaluations . . . ."<sup>185</sup> The Supreme Court has expressly stated that it is not competent to entertain argu-

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*ward Science is Yes, but—*, SCIENCE, Jan. 15, 1982, at 270 (quoting National Science Board annual report, *Science Indicators 1980*); see *SPLICING LIFE*, *supra* note 31, at 71.

181. *Human Genetic Engineering Hearings*, *supra* note 2, at 155.

182. Annas, *At Law: Of Monkeys, Man, and Oysters*, HASTINGS CENTER REP. 20, 22 (Aug. 1987).

183. *Marbury v. Madison*, 5 U.S. (1 Cranch) 137 (1803).

184. See *supra* notes 72-73 and accompanying text. Absent a strong countervailing constitutional argument, one commentator suggests that *Diamond v. Chakrabarty*, 447 U.S. 303 (1980), indicates the Supreme Court would hold that human inventions are patentable. Westerhoff and Morrison, *Patent Applications Will Be Entertained for New Organisms*, LEGAL TIMES, June 15, 1987, at 17, col. 3. Since *Chakrabarty*, Chief Justice Burger and Justice Stewart from the majority and Justice Powell, who joined in the dissent, have retired from the Court.

185. Note, *supra* note 8, at 531.

ments regarding the social policy issues surrounding the hazards of recombinant DNA research.<sup>186</sup> Some state courts have also concluded that they are ill-equipped to grapple with the moral and ethical issues inherent in genetic engineering.<sup>187</sup>

## B. Legislative Action

Congress is a more appropriate body than the courts for determining whether human inventions should be allowed to be patented.<sup>188</sup> Although the courts have given a very broad interpretation to patent laws, Congress is empowered to make patent protection unavailable to an entire class of otherwise patentable subject matter.<sup>189</sup> Based on its assessment of moral and ethical concerns, Congress may therefore prohibit the patenting of all inventions involving human beings who possess genetically engineered characteristics.<sup>190</sup> Even if such patents are permitted, state or federal laws may restrict a patent holder's right to manufacture, use and sell his invention.<sup>191</sup>

A flat prohibition on patenting new human genetic material is a drastic measure, and is unnecessary to regulate effectively the use of such products. Instead, Congress could prevent most abuses by prohibiting the manufacture of animal-human hybrids and sub-humans and by providing how patented human inventions may be sold. Another set of laws could create a remedy for parties with patented genotypes who have suffered injuries, such as discrimination, as a result of their genetic status.

Unless amended, the Patent Act cannot be used to regulate how a patent is practiced, but Congress may invoke powers granted under the Commerce and Spending Clauses to restrict the manufacture, use, and

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186. See *supra* note 178.

187. *E.g.*, *Zepeda v. Zepeda*, 41 Ill. App. 2d 240, 259-63, 190 N.E.2d 849, 858-59, (1963) *cert. denied* 379 U.S. 945 (1964) (creation of legal action for wrongful life against genetic engineers is decision for state legislature).

188. "Congress is free to amend § 101 so as to exclude from patent protection organisms produced by genetic engineering." *Chakrabarty*, 447 U.S. at 316-318.

189. The Atomic Energy Act of 1946 and subsequent legislation prohibit the granting of patents for inventions involving atomic weapons. 42 U.S.C. § 2181 (a) reads, "No patent shall . . . be granted for any invention or discovery which is useful solely in the utilization of special nuclear material or atomic energy in an atomic weapon." 42 U.S.C.A. § 2181(a) (West 1973).

190. Some members of Congress have introduced legislation to halt the patenting of new life forms. A proposal to amend the Patent Act would have prohibited the patenting of genetically modified animals for two years. H.R. 3119, 100th Cong., 1st Sess. 134 CONG. REC. H7206 (daily ed. August 5, 1988), see H.R. REP. NO. 888, 100th Cong., 2d Sess. (1988). Although H.R. 3119 was not enacted, H.R. 1556 was recently introduced to amend Title 35 of the United States Code to provide that human beings are not patentable subject matter. H.R. 1556, 101st Cong., 1st Sess. (1989). At the time of publication of this Note, enactment of H.R. 1556 was pending.

191. *Patterson v. Kentucky*, 97 U.S. 501 (1878) (state statute prohibiting sale of patented burning oil upheld); *Decker v. FTC*, 176 F.2d 461 (D.C. Cir.) *cert. denied*, 338 U.S. 878 (1949) (fraudulent claims concerning function of patented article held to be violation of federal law).

sale of patented human inventions. Wherever distribution of patented human products is of an interstate character, Congress is empowered to control the manufacture of patented products.<sup>192</sup> Congress could act under the Commerce Clause to prohibit employment discrimination by private parties on the basis of patented genetic makeup.<sup>193</sup> Moreover, state statutes (such as eugenics laws) that conflicted with federal commerce regulations would be preempted.<sup>194</sup>

Congress could also use its spending power to discourage research activities of uncertain value.<sup>195</sup> The federal government is a significant contributor of funding for genetic engineering research.<sup>196</sup> By cutting off funding for research into certain types of human inventions, Congress could discourage their development without prohibiting the patenting of all human inventions. State legislatures could act to prohibit patented products of human genetic engineering technology. In light of the danger of diminishing genetic variety presented by the proliferation of "desirable" or "superior" human inventions, a state's interest in banning the local use of genetic engineering technology might be found compelling.<sup>197</sup> Additional important governmental interests including ensuring personal autonomy, protection of personal privacy, elimination of deleterious genes from the gene pool, preventing pain and suffering, and reducing the numbers of people with genetic disorders who must depend on state-funded services might support state regulation of the uses of genetic engineering in humans.<sup>198</sup>

State and local governments, concerned over the consequences of commercial genetic engineering, have already acted to control biotechnology research activities within their jurisdictions.<sup>199</sup> Municipal ordi-

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192. U.S. CONST. art. I, § 8, cl. 3 ("The Congress shall have Power . . . To regulate Commerce with foreign nations, and among the several States, and with the Indian Tribes.") *Cf.* *Champion v. Ames*, 188 U.S. 321 (1903) (upholding congressional act prohibiting transport of illegal lottery tickets within channels of interstate commerce).

193. *Cf.* *Katzenbach v. McClung*, 375 U.S. 294 (1964) (Congress empowered to regulate discriminatory practices of restaurant serving interstate travelers due to effect on interstate commerce).

194. *Cf.* *Hines v. Davidowitz*, 312 U.S. 52 (1941) (preemption of state alien registration law that stood "as an obstacle to the accomplishment and execution of the full purpose and objectives of Congress").

195. "The Congress shall have Power To . . . provide for the . . . general Welfare of the United States . . ." U.S. CONST. art. I, § 8, cl. 1.

196. In fiscal year 1983, the federal government spent \$511 million on basic biotechnology research. U.S. CONGRESS OFFICE OF TECHNOLOGY ASSESSMENT, *COMMERCIAL BIOTECHNOLOGY: AN INTERNATIONAL ANALYSIS (SUMMARY)* 19 (1984).

197. *Cf.* Note, *supra* note 8, at 561.

198. *See id.* at 498.

199. *See* N.Y. PUB. HEALTH LAW §§ 3220-3222 (McKinney 1985); CAMBRIDGE, MASS. CODE art. III; § 11-7 et. seq. (1977); BERKELEY, CAL. ORDINANCES no. 5010-N.S. (1977); BOROUGH OF PRINCETON, N.J. CODE ch. 26A, § 1 (1978); AMHERST, MASS. BY-LAWS art. III, § 10 (1978); WALTHAM, MASS. GENERAL ORDINANCES ch. 22 (1981). One township has

nances restricting gene splicing research have been enacted in communities where biological research and commercial biotechnology enterprises are now propagating. These laws fill a regulatory gap created by the limited applicability of federal guidelines. In these localities, institutions engaging in such research must obtain a permit from the city and are subject to inspection by city officials to ensure their compliance with federal and local law.

Regulations such as those contained in the local ordinances can be an effective check on human genetic research. Such regulation in order to prevent constitutional violations would minimize the need to prohibit patenting an entire class of otherwise patentable inventions.

### C. Administrative Regulation

The National Institute of Health's guidelines for research involving recombinant DNA molecules are currently the only regulations governing laboratory studies involving transgenic animals produced through genetic engineering.<sup>200</sup> A second generation of the Recombinant DNA Advisory Committee<sup>201</sup> currently oversees implementation of the NIH guidelines.<sup>202</sup> New agencies, however, that are specifically suited to the peculiar problems commercialization of patented human inventions is likely to bring will be needed to establish guidelines for the manufacture, use, and sale of patented human genotypes. In addition, new agencies may be needed to enforce trade practices and standards of quality of patented products for industry and commerce.

Cognizant of the rapid pace of technological progress, legislatures and administrative agencies are contemplating how future products of biotechnology will be regulated.<sup>203</sup> A panel composed of scientists, industry representatives, and religious leaders might be effective in providing guidelines for commercial development of genetic engineering and in assessing the impact of new patented human inventions. Whatever mechanism is employed to regulate the development of human inven-

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prohibited the use within its borders of humans as experimental subjects in recombinant DNA research. *See id.* § 22-2.

200. Compliance with these guidelines is mandatory for any scientist or institution receiving federal funding for research. *See* Guidelines for Research Involving Recombinant DNA Molecules, 51 Fed. Reg. 16,958 et. seq. (May 7, 1986). Industry has voluntarily followed these guidelines, with no reported violations since their adoption in 1976. *Patent Hearings, supra* note 15, at 434 (testimony of Geoffrey M. Karry).

201. One-third of the committee's twenty-five members must specialize in molecular biology or a related field; at least six must be scientists in other related disciplines, and at least six must be authorities on public health, law, the environment, or public policy. U.S. CONGRESS, OFFICE OF TECHNOLOGY ASSESSMENT, IMPACTS ON APPLIED GENETICS—MICRO-ORGANISMS, PLANTS, AND ANIMALS 213 (1981).

202. *SPLICING LIFE, supra* note 31, at 12.

203. *See id.*, at 87 (recommending creation of Genetic Engineering Commission to deal exclusively with biotechnology issues).

tions should encourage their patenting.<sup>204</sup> Disclosures made in patent applications provide government the ability to foresee technological developments and to determine what areas will require regulation.<sup>205</sup> Most importantly, patent laws provide inventors of biological inventions the protection necessary to prevent misappropriation of their work and to encourage continued research.

## VI. Conclusion

While the patenting of human inventions may raise serious ethical questions, the granting of such patent rights would not violate the Constitution. A patent—an intangible property interest—grants its holder only the exclusive right to her discovery. An inventor of a new human life form does not have rights in any genotype other than the product of her genetic manipulation. Nor does the scientist have a possessory interest in the patented product, the resulting physical characteristic. Consequently, the rights granted under a patent would not result in illegal subjugation of the individual possessing the genotype. A patent on human genetic material would thus not constitute a badge of slavery.

Certain exercises of these patent rights by the inventor, however, would violate fundamental constitutional rights. Practices of a patent that greatly restricted the external autonomy of one who possessed the patented genotype, as would the creation of animal-human hybrids or sub-humans, would be tantamount to imposing badges of slavery on people, a practice prohibited by the Thirteenth Amendment. Mild restraints on an individual's internal autonomy, however, such as disclosure of the engineered genotype in a patent or implantation of a patented gene to correct a disorder, would likely be constitutional. Thus, the degree of restriction and autonomy that practice of a patented human invention would have seems a useful measure of its permissibility.

In addition, patent protection of human inventions would impinge on the fundamental right to procreate and on privacy interests in maintaining confidentiality in the genetic constitutions of those possessing the patented gene. As such, amendment of the patent statute might be necessary to preserve the constitutionality of provisions giving inventors of

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204. Denying patents on engineered genotypes would cause inventors to seek other forms of intellectual property protection. See, e.g., Kayton, *Copyright in Living Genetically Engineered Works*, 50 GEO. WASH. L. REV. 194 (1982) (protection of products of genetic engineering under copyright law). Because activities cloaked in the secrecy necessary for trade secret production are more difficult to oversee, patents serve a public interest in disclosing research activities being conducted.

205. See Note, *Patents—A Live, Man-Made Micro-Organism is Patentable Subject Matter Under 35 U.S.C. § 101*, 30 DRAKE L. REV. 635, 647-49 (1980-81) (promoting use of the patent system assures public disclosure of research, which should not only serve to educate the public and allay fears of genetic engineering, but also allow the public and Congress to identify those areas where prohibitions may be advisable).

human inventions a remedy for patent infringement. An exemption from liability would protect the privacy rights of recipients of patented genetic material. Another amendment restricting public access to information contained in the patent regarding a person's genetic constitution would safeguard against intrusions on privacy.

Furthermore, the availability of patented human inventions in the marketplace may give rise to preferences for individuals having certain genetic constitutions. This preference may be reflected in unconstitutional state actions requiring correction of genetic disorders and in policies promoting the propagation of certain state-sponsored genotypes. This preference might also take the form of unconstitutional discriminatory private employment practices.

Unconstitutional practices of such patents and the development of unconstitutional actions may diminish a human invention's utility, but these potential consequences do not render inventions involving human beings unpatentable. Therefore, the PTO's policy of prohibiting the patenting of human beings is unfounded. Moreover, the PTO is not competent to perform the constitutional balancing necessary to assess a human invention's patentability. Imposition of a requirement that all an invention's uses be constitutional is beyond the PTO's statutory authority.

Congress could prevent the adverse consequences of patenting human inventions without prohibiting them altogether by regulating their manufacture, use, and sale. In addition, myriad administrative agencies will continue to oversee genetic engineering research. With the exception of a statute prohibiting patents on nuclear weapons, the U.S. patent system is devoid of safety, ethical, or economic judgments. Patent laws should remain morally and ethically neutral and continue to "promote the progress of science and useful arts."

In the words of Professor Bernard Davis, "We can serve society best not by blocking any particular knowledge but by better controlling its applications . . . . [I]n the application of molecular genetics to man, where enormously beneficial results are appearing, I do not yet see any threats from which society needs protection."<sup>206</sup>

The PTO's contention that patenting genetically engineered human beings is unconstitutional is devoid of constitutional analysis and is wrong. Claims of inventions including a human being are patentable, and such patents are constitutional. Superficial treatment of inventions holding great promise for curing thousands of human genetic disorders inhibits promotion of the useful arts. While the PTO's policy attempts to prevent the problems that patenting human beings may bring, its effect will be to hinder important biomedical research. The PTO's policy could discourage significant medical advancements in related technologies and

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206. *Human Genetic Engineering Hearings*, *supra* note 2, at 469 (statement of Bernard D. Davis, Professor of Bacterial Physiology, Harvard University Medical School).

could perpetuate public fear of technology and mistrust of science. Human genetic engineering holds great promise, and any regulation of its use should also encourage its continued development.

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